Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

K123862

1/3

MAR 1 2 2013

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary of Safety and Effectiveness

Sponsor:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person:

Joanna L. Surma
Associate Project Manager, Regulatory Affairs
Telephone: (574) 371-1642
Fax: (574) 372-4605

Date:

13 December 2012

Trade Name:

Zimmer Nexel Total Elbow

Common Name:

Total Elbow Prosthesis

Classification

21 CFR § 888.3150
Elbow joint metal/polymer constrained cemented prosthesis

Product Code:

JDC – Prosthesis, Elbow, Constrained, Cemented

Predicate Device:

Coonrad/Morrey Total Elbow, manufactured by Zimmer, K001989, cleared 25 July 2000

Coonrad/Morrey Total Elbow, manufactured by Zimmer, K053189, cleared 9 December 2005

Device Description:

The Zimmer Nexel total Elbow is a total elbow prosthesis designed for use with bone cement. It is available in multiple sizes and in right and left configurations.

How the Device Functions: The Zimmer Nexel Total Elbow is an implant designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a constrained device assembly and consists of the following components: humeral component, ulnar component, humeral bearing-A, ulnar bearings-B, axle pin and humeral screws.

The Following Scientific Concepts, Design Features and Physical Properties form the Basis for the Zimmer Nexel Total Elbow: The humeral component has a humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal, an anterior flange designed to accept a

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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bone graft and limit torsional and posterior migration, a humeral yoke with rounded corners to avoid the creation of stress risers within the medial and lateral humeral supracondylar columns, and plasma spray region to enhance fixation to bone cement within the medullary canal, and to improve fatigue strength. The ulnar component has an ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal, an ulnar eye that is both highly polished and nitrogen-enriched to limit wear of the apposing polymer bearings, and plasma spray region to enhance fixation to bone cement within the medullary canal. Bearings A and B are designed to broadly distribute joint reaction forces.

Materials Used: The humeral and ulnar components are made of a titanium alloy, the bearings A and B are made of Vitamin E highly cross-linked polyethylene, and the humeral screws and axle pin are made of a cobalt-chromium-molybdenum alloy.

Comparison to the Predicate: The proposed device (Zimmer Nexel Total Elbow) and the predicate device (Coonrad/Morrey Total Elbow) have the same intended use and similar indications for use. The proposed device humeral and ulnar components are very similar in terms of materials used and design/dimensions to the predicate device humeral and ulnar components. The primary differences between the proposed and predicate devices are that the proposed device bearing components are made of Vitamin E highly cross-linked polyethylene (the predicate device bearing components are made of ultra-high molecular-weight polyethylene), and the proposed device has bearings that articulate on both the outer and inner diameters of the ulnar eye (the predicate device has bearings that articulate on the inner diameter of the ulnar eye). Additionally, the proposed device uses screws and a 1-part axle pin to fix the bearings in place, while the predicate device uses a 2-part (snap-fit) axle pin.

Intended Use:

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

Caution: This device is intended for cemented use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary of Safety and Effectiveness – Zimmer Nexel Total Elbow

Comparison to Predicate Device:

The Zimmer Nexel Total Elbow is substantially equivalent to the predicate device in terms of form and function. The Zimmer Nexel Total Elbow and the predicate device share similar intended uses and indications for use.

Performance Data:

Non-Clinical Performance Testing Conducted:

- Stem Fatigue Testing
- Wear Testing
- Durability Testing
- Modular Connection Fatigue Testing

Non-Clinical Performance Testing Conclusions:

Non-clinical testing demonstrated that the New Zimmer Total Elbow meets performance requirements as defined by Design Control activities and is substantially equivalent to the predicate device in terms of safety and efficacy.

In this case, clinical data and conclusions were not needed to demonstrate substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Zimmer, Incorporated
% Ms. Joanna L. Surma
Associate Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Letter dated: March 12, 2013

Re: K123862
Trade/Device Name: Zimmer Nexel Total Elbow
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: JDC
Dated: December 13, 2012
Received: December 14, 2012

Dear Ms. Surma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number (if known): K123862

Device Name:

Zimmer Nexel Total Elbow

Indications for Use:

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
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- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

CAUTION: This device is intended for cemented use only.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

K123862

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

V.1

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Zimmer, Incorporated
% Ms. Joanna L. Surma
Associate Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Letter dated: March 12, 2013

Re: K123862
Trade/Device Name: Zimmer Nexel Total Elbow
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: JDC
Dated: December 13, 2012
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Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K123862

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Peter Allen 3/10/13
Branch Chief Sign-Off	Casey Hanley
Division Sign-Off	Mark N. Melkerson -S 2013.03.12 17:14:06 -04'00'

f/t:PGA:tmj:3/12/13:eaf4:3/12/13

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Indications for Use

510(k) Number (if known): K123862

Device Name:

Zimmer Nexel Total Elbow

Indications for Use:

Indications for use include:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices

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x x x COMMUNICATION RESULT REPORT (MAR. 14. 2013 6:37PM) x x x

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : MAR. 14. 2013 6:34PM E MODE	OPTION	ADDRESS	RESULT	PAGE
3787 MEMORY TX		915743724605	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Zimmer, Incorporated
% Ms. Joanna L. Surma
Associate Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Letter dated: March 12, 2013

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Trade/Device Name: Zimmer Nexel Total Elbow
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: JDC
Dated: December 13, 2012
Received: December 14, 2012

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name **Peter Allen**

Subject: 510(k) Number **K123862**

To: The Record

Please list CTS decision code **SE**

- o Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- o Hold (Additional Information or Telephone Hold).
- X Final Decision (**SE**, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

o	NO	NSE for lack of predicate
o	NI	NSE for new intended use
o	NQ	NSE for new technology that raises new questions of safety and effectiveness
o	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
o	NP	NSE for lack of performance data
o	NS	NSE no response
o	NL	NSE for lack of performance data AND no response
o	NM	NSE pre-amendment device call for PMAs (515i)
o	NC	NSE post-amendment device requires PMAs
o	NH	NSE for new molecular entity requires PMA
o	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			X
Is clinical data necessary to support the review of this 510(k)?			X
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

Rev. 9/20/12 – added digital concurrence table

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)		
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age<=21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days -< 2 years old)		X
Child (2 years -< 12 years old)		X
Adolescent (12 years -< 18 years old)		X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		X
Nanotechnology		X
Mobile Application		X
MR Conditional		X
Device Contains Battery		X
Companion Diagnostic		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	X

Regulation Number	Class*	Product Code
21 CFR 888.3150	II	JDC

(*If unclassified, see 510(k) Staff)

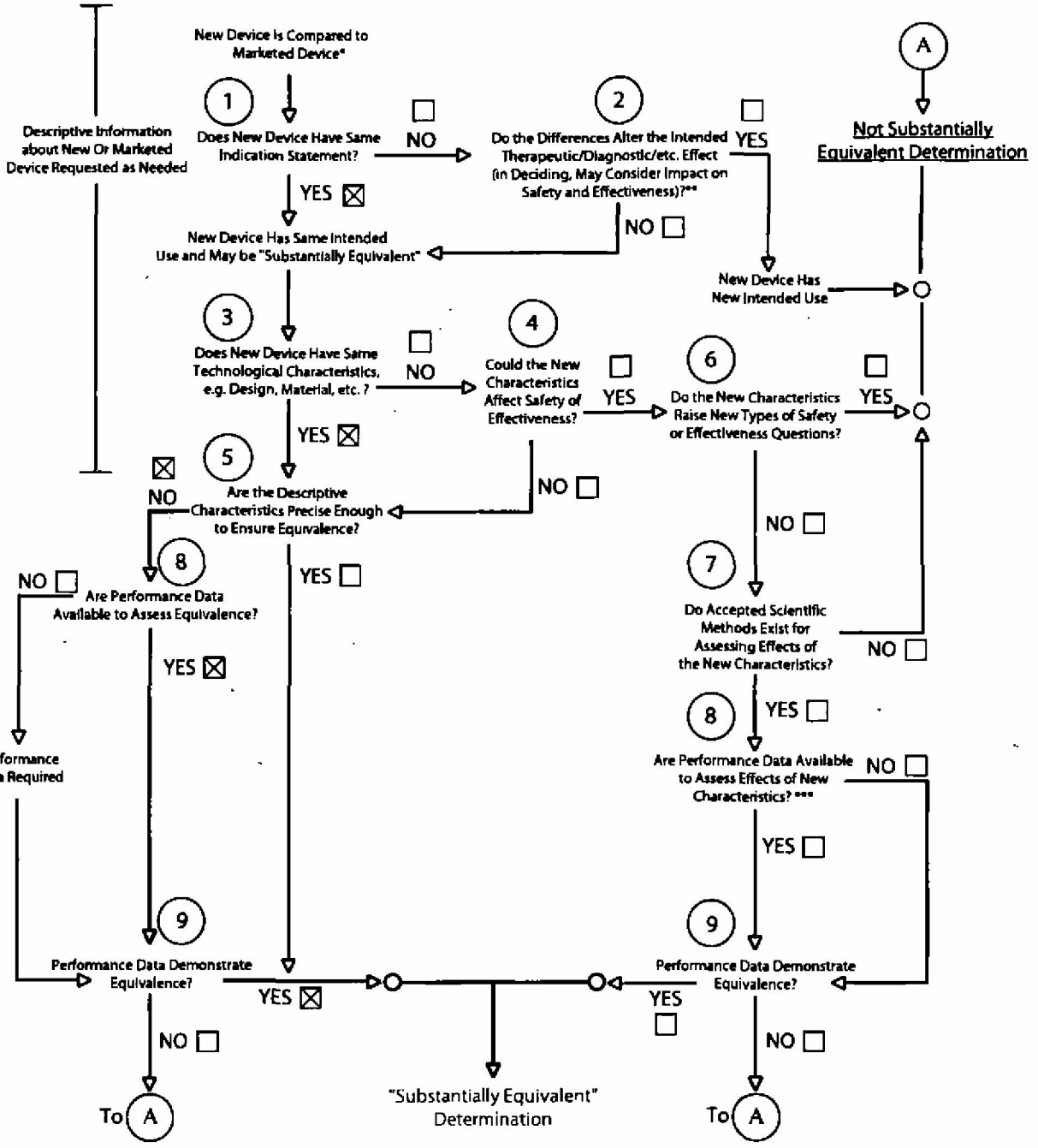
Additional Product Codes:

Digital Signature Concurrence Table	
Reviewer Sign-Off	Peter G. Allen 2013.03.11 09:13:11 -04'00'
Branch Chief Sign-Off	Casey Hanley -S 2013.03.12 09:22:09 -04'00'
Division Sign-Off	Mark N. Melkerson -S 2013.03.12 17:12:09 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



SE

* 510(k) Submissions compare new device to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or literature.

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K123862

Date: March 8, 2013
To: The Record
From: Peter G. Allen, M.S.; Biomedical Engineer
510(k) Holder: Zimmer, Inc.
Device Name: Zimmer Nexel Total Elbow
Contact: Ms. Joanna Surma, MS, RAC, Regulatory Affairs, Associate Project Manager
Phone: 574-371-1642
Fax: 574-372-4605
Email: joanna.surma@zimmer.com

Office: ODE
Division: DOD
Branch: JFOB

I. Purpose and Submission Summary

The 510(k) holder would like to introduce Zimmer Nexel Total Elbow into interstate commerce. The Nexel Total Elbow is a constrained elbow prosthesis intended for cemented use. This is a new device to the U.S. market.

The sponsor provided, via interactive review, additional information including EtO residual testing results, details on colorants used in their instrumentation, updated labeling to include appropriate MR statements, additional discussion regarding the differences in range of motion between their device and the predicate device, edits to all relevant parts of the submission to replace the device descriptive term "semi-constrained" with the appropriate term "constrained", and revisions to the 510(k) Summary.

The materials, design, sizes, indications, intended use, sterilization, and packaging, for the subject device are similar and/or identical to legally marketed predicate devices. The sponsor has provided adequate characterization in terms of device design, size, material, intended used and testing to demonstrate that the subject device components are equivalent to marketed predicate devices. **Therefore, I recommend SE.**

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary or 510(k) Statement	x		
Standards Form	x		

III. Device Description

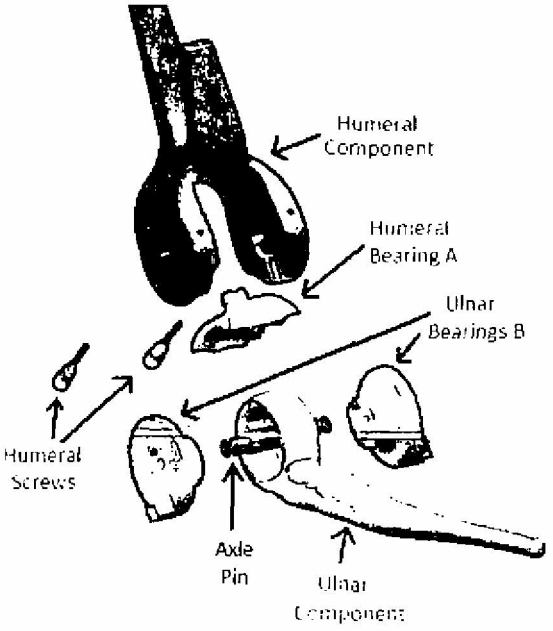
	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

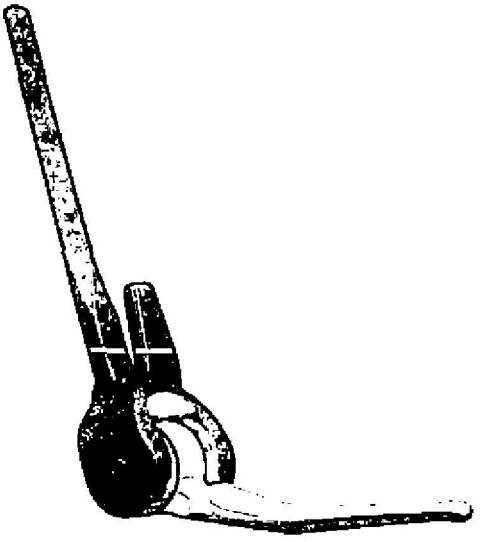
Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

	Yes	No	N/A
Is the device an implant (implanted longer than 30 days)?	x		
Does the device design use software?		x	
Is the device sterile?	x		
Is the device reusable (not reprocessed single use)?		x	
Are "cleaning" instructions included for the end user?			x

The Zimmer Nexel Total Elbow is designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a constrained device assembly and consists of a humeral component, an ulnar component, a humeral bearing-A, 2 ulnar bearings-B, an axle pin and 2 humeral screws.



Exploded view



Assembled view

Humeral Component

The humeral component is made from wrought *Tivanium* alloy (Ti-6Al-4V, ASTM F136) and has the following major design features: a stem, an anterior flange, a yoke and plasma spray regions.

The humeral stem is intended to be implanted with bone cement into the patient's humeral medullary canal. It has a triangular cross-section, which is designed to prevent rotation of the humeral component within the patient's medullary canal; and, it is straight along its proximal-distal axis to conform to the straight shaft of the distal humeral medullary canal.

The humeral anterior flange is designed to accept a bone graft, which is wedged between the anterior flange and the exterior cortical bone of the humeral shaft. This anterior flange and bone graft combination are intended to improve both antirotational stability and posterior migration of the humeral component, thereby resisting stem loosening.

The humeral yoke has rounded corners (as opposed to angular) on its proximal surface in order to prevent stress risers (that are often associated with bone preparation cuts required for angled corners abutting bone). This rounded yoke design is intended to preserve the strength of (and avoid fracture of) the medial and lateral supracondylar columns. The yoke walls also house partially threaded holes with Spiralock technology, which

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engage with the humeral screws.

The humeral component has several regions covered in plasma spray (which is contained within the Plasma Sprayed Titanium-6Al-4V Alloy Coating Material Master File, FDA Ref: MAF-1909, Letter of Authorization can be found in Section 21). The plasma spray regions are designed to increase the coefficient of friction between the implant and the bone cement, thereby improving anti-rotational stability and aiding in resistance to movement of the implant with respect to the humerus.

In addition to the aforementioned major design features, the humeral component also includes the following features to accept the axle-pin and bearings A and B: v-grooves at the base of the keyways to accept the axle-pin, a hole to accept humeral bearing-A and two keyways to accept ulnar bearings-B.

The Nexel Total Elbow's allowable flexion arc from (b)(4) , comply well with the 0-146° flexion arc and +/-3°-5° range of varus/valgus angulation of a normal, healthy elbow reported in the referenced studies summarized in Zimmer's *BIOMECHANICS RATIONALE FOR THE LOADING OF TOTAL ELBOW PROSTHESIS DURING IN VITRO SIMULATIONS* document (included in the original submission and also provided in Attachment 3 of their 2/27/13 email). While the predicate Coonrad/Morrey implant assembly allows (b)(4)) flexion and up to (b) of v/v laxity, the normal elbow doesn't allow (due to soft and hard tissue limitations) this much flexion and functions normally within the (b)(v/v angulation range provided by both the Nexel and the C/M.

The Nexel Total Elbow was designed to provide at least as much of the necessary flexion and v/v laxity as required of a normal, healthy elbow while maximizing the thickness and optimizing the location and form of the Vitamin-E UHMWPE Bearings to provide improved wear resistance and longer-term load-bearing capability as compared to the predicate device. Thus, any flexion and v/v angulation deemed unnecessary for a full healthy elbow range of motion was traded for optimization of device performance; this is further substantiated by the results of the head-to-head Wear and Durability tests, wherein both (Nexel and predicate) devices were subjected to high-loading over large flexion arcs with induced v/v angulation to simulate clinically-relevant, yet aggressive, long-term use in-vivo.

Ulnar Component

The ulnar component is made from wrought *Tivanium* alloy (Ti-6Al-4V, ASTM F136) and has the following major design features: a stem, an eye, and a plasma spray region.

The ulnar stem is intended to be implanted with bone cement into the patient's ulnar medullary canal. It has a quadrangular cross-section, which is designed to prevent rotation of the ulnar component within the patient's medullary canal; and, it is curved along its proximal-distal axis to conform to the curved shaft of the proximal ulnar medullary canal.

The ulnar eye is both highly polished and nitrogen-enriched (as recommended in Section J, Titanium Articular Surface Coatings, of *Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented; Guidance for Industry and FDA*) to limit wear of the opposing Bearings A and B upon which it articulates. This a nitrogen ion implantation (also known as nitriding) process to increase titanium alloy surface hardness on the region specified in the engineering drawings (both inner and outer articulating surfaces of the ulnar eye – as clarified in phone call with sponsor on 2/22/13 and their email of 2/27/13). The articulating surfaces of the ulnar component are polished to an Ra value of (b)(4) or less and the articulating surfaces of the bearings A and B are machined to an Ra value of (b)(4) or less to provide for smooth articulating surfaces.

The proximal portion of the ulnar stem is covered with plasma spray (which is contained within the Coatings Characterization of Orthopedic Titanium 6Al4V Coatings Material Master File, FDA Ref: MAF-652, Letter of Authorization can be found in Section 22). The plasma spray region is designed to increase the coefficient of friction between the implant and the bone cement, thereby improving anti-rotational stability and aiding in resistance to movement of the ulnar stem with respect to the ulna.

The ulnar component is side-specific, meaning that there is a left ulnar component and a right ulnar component available for every size offering.

Humeral Bearings-A

The Humeral Bearing-A is made from Vivacit-E (Vitamin E [α-tocopherol] stabilized, highly crosslinked ultra-high molecular weight polyethylene), which is contained within the Vitamin E Stabilized HXPE Material Master File authored by Zimmer (FDA Ref: MAF-1868). Humeral bearing-A is designed to articulate against the ulnar

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component throughout most of the humeroulnar joint range of motion, and has the following major design features: concave articulation surface, anterior and posterior ridges, a fixation peg, four peripheral bumps, and medial and lateral rails.

The humeral bearing-A concave articulation surface is intended to, along with the articulation surface of the ulnar bearings-B, allow for load sharing from the ulnar component onto humeral bearing-A throughout most of the range of motion of the humeroulnar joint. The posterior ridge specifically supports high-flexion motions.

The humeral bearing-A fixation peg is designed to mate to the hole at the proximal base of the humeral yoke with a press (not a snap) fit, which is intended to limit motion between humeral bearing-A and the humeral yoke.

The humeral bearing-A has 4 peripheral bumps that are designed to mate against the interior walls of the humeral yoke with a press-fit, which is intended to limit motion (and therefore backside wear) of the humeral bearing-A relative to the humeral yoke.

The humeral bearing-A medial and lateral rails are designed to allow clearance for (as opposed to a direct mate with) ulnar bearings-B, which directly mate to the humeral yoke and to the axle pin.

Ulnar Bearings-B

The ulnar bearings-B (two per implant assembly) are made from Vivacit-E (Vitamin E [α-tocopherol] stabilized, highly crosslinked ultra-high molecular weight polyethylene), which is contained within the Zimmer Vitamin E Stabilized HXPE Material Master File (FDA Ref: MAF-1868). Ulnar bearings-B are designed to articulate against the ulnar component throughout the entire humeroulnar joint range of motion, and have the following major design features: articulation surface, anti-rotation key, through-hole and compressible semi-circle.

The ulnar bearings-B articulation surface is intended to, along with the articulation surface of the ulnar bearing-A, allow for load sharing from the ulnar component onto humeral bearing-B throughout the range of motion of the humeroulnar joint.

The ulnar bearings-B anti-rotation keys mate into the humeral yoke keyways with a press-fit to limit translational and rotational motion of ulnar bearings-B with respect to the humeral component.

The compressible semi-circle of one ulnar bearing-B is designed to align with the compressible semi-circle of the second ulnar bearing-B such that a nearly full circle is created. This design feature is intended to ensure proper alignment of ulnar bearings-B with respect to each other (during assembly of ulnar bearings-B to the axle pin using the ulnar bearing assembly tool) and, after proper assembly to the axle pin, to the humeral yoke keyways. Due to the fact that the compressible semi-circle is more easily deformed than the broad, apposing faces of ulnar bearings-B, it creates a press-fit between the ulnar bearings-B and between each ulnar bearing-B and the opposing interior walls of the humeral yoke. This press-fit is intended to limit mediolateral motion of the ulnar bearings-B along the axle-pin, thereby limiting backside wear of the ulnar bearings-B.

The ulnar bearings-B through-hole mates around the axle pin with a press-fit intended to limit motion of ulnar bearings-B with respect to the axle pin, and thus limit backside wear of ulnar bearings-B. The position of the through-hole is eccentric (with respect to the outer diameter of ulnar bearings-B) in order to place the largest cross-section of Vivacit-E material in opposition to the highest loads (joint reaction forces) induced throughout the flexion-extension cycle of the humeroulnar joint.

Axle Pin

The axle pin is made from Zimaloy (Cobalt-Chromium-Molybdenum Alloy, ASTM F75), is designed to remain in a fixed position (not translate nor rotate) throughout the entire humeroulnar joint range of motion, and has the following major design feature: v-groove.

The v-groove is designed to mate with the taper of the humeral screws that, upon screw thread engagement in the humeral yoke, rigidly compresses the axle pin against the humeral yoke. Additionally, the axle pin is designed to rigidly mate with ulnar bearings-B, the humeral screws and the humeral yoke, creating a rigid assembly along which joint reaction forces are intended to be shared.

Humeral Screws

The humeral screws (two per implant assembly) are made from Zimaloy (Cobalt-Chromium-Molybdenum Alloy, ASTM F75), are designed to remain in a fixed position throughout the entire humeroulnar joint range of motion, and have the following major design features: headless, threads, pilot and taper.

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The humeral screw threads engage with threads of the humeral yoke while the humeral screw pilot engages a hole in the wall of the humeral yoke and the humeral screw taper engages with the axle pin v-groove, compressing the ends of the axle pin against the v-groove at the base of the humeral yoke keyway.

The humeral screws are headless, a feature that allows the humeral screws to countersink into the humeral yoke, which is intended to ensure the constant application of a clamp-load to the axle-pin and to avoid soft tissue impingement or irritation associated with a protruding screw head.

While the humeral screws are designed to apply a consistent clamp-load to the axle pin, they are not directly loaded by any compressive joint reaction force during the flexion-extension cycle (this design feature is intended to avoid screw back-out by not allowing any complete transverse load-reversal across the humeral screw threads). Instead, compressive forces are transmitted from the ulnar implant component to the ulnar bearings-B to the axle pin to the v-grooves at the base of the humeral yoke keyways and finally throughout the humeral component.

Other
The metallic humeral and ulnar components are machined from (b)(4)
(b)(4)

The poly bearings (humeral bearing-A and ulnar bearings-B) are machined from (b)(4)
(b)(4)

The CoCr humeral screws and axle pins are machined (b)(4)
(b)(4)

Zimmer Nexel Total Elbow components are not compatible with any other devices outside the subject Zimmer Nexel Total Elbow system.

All Zimmer Nexel Total Elbow humeral component sizes are designed to mate with all Zimmer Nexel Total Elbow ulnar component sizes. The axle pin size 4, humeral bearing-A size 4, and ulnar bearings-B size 4 are designed to mate with all size 4 humeral components. The axle pin size 5/6, humeral bearing-A size 5/6, and ulnar bearings-B size 5/6 are designed to mate with all size 5 and size 6 humeral components. The humeral screws are designed to mate with all Zimmer Nexel Total Elbow humeral components and axle pin sizes.

Representative engineering drawings are provided in the Device Description section of the submission.

The sponsor has provided a table of class I and class II instrumentation applicable to the use of this device. Materials include predominantly stainless steel, as well as Radel, Ultem, LDPE, and silicone.

Two instruments were identified as having colorant additives in them. These were an Ultem screw driver handle and a silicone screw removal driver handle. The screw driver is a single-use only disposable device. The same colorants used in the polymeric instrument components have been used in other Zimmer device systems including K040593 and K933785.

Reviewer Comment: *No information on colorants was provided in the original submission. In an interactive review teleconference (and email) with the sponsor on 2/22/13 the sponsor was asked to either identify predicate device systems that utilize these colorants (if any) or provide biocompatibility information. In their email response dated and received on 2/27/13 the sponsor identified that two colorants were used with the subject instrumentation. They also identified two predicate device systems that have utilized these same colorants in similar instrument components. The colorants were not identified by name but since they are just used in instrument handles and have been used for 9 and 20 years, respectively (and one is disposable, single-use only), no additional information will be asked for at this time. Therefore, the response is acceptable; and no*

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further information is required to 'grandfather' in these colorants. The sponsor was notified, however, that in the future any new colorants will need biocompatibility information provided in the 510(k) of the associated device system.

This device description is now adequate as information on colorants used in the instrumentation has been provided. The device description is adequate to demonstrate the similarities and differences in device design to the referenced predicate devices, and in helping to establish an SE determination based on these comparisons.

IV. Indications for Use

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living.
- Post-traumatic lesions or bone loss contributing to elbow instability.
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis.
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain.
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis.
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus.
- Revision arthroplasty.

CAUTION: This device is intended for cemented use only.

Reviewer Comment: *The indications are the same or similar to those identified in the predicate device submissions. The indications are consistent across the Package Insert, 510(k) Summary, and Indications for Use form. This is acceptable.*

V. Predicate Device Comparison

K001989, Coonrad/Morrey Total Elbow, Zimmer, Inc.
K053189, Coonrad/Morrey Total Elbow, Zimmer, Inc.

Reviewer Comment: *The sponsor has identified acceptable predicate devices.*

VI. Labeling

Labeling includes draft labels, a draft package insert (IFU), separate IFU for cleaning and sterilization of non-sterile instrumentation (provided as a response to RTA deficiencies), and a draft surgical technique.

Symbols on the outer package labels are paired with appropriate descriptive text. Package labels appear to contain all necessary information including the prescription use only symbol (Rx symbol), sterility, sterilization method, single use only statement, cemented use only statement, caution statement (see instructions for use), material, quantity, expiration date (10 years and 5 years), size, name, lot number, catalogue number, sponsor name, and address. The outer package labels appear appropriate.

A specific package insert for the Nexel Total Elbow was provided which covers the components of this subject submission. It contains all appropriate sections, including sponsor name and contact information, device name, cemented use only statement, prescription use statement, device description, materials, indications, contraindications, warnings, precautions, adverse events, and sterility. Appropriate MR language noting that the Nexel Total Elbow has not been evaluated for safety and compatibility, nor tested for heating or migration in the MR environment, *is* included in the revised package insert, provided via email on 2/27/13. Resterilization of UHMWPE implants is specifically not recommended.

Sterilization/resterilization parameters for metal implant components and instruments are provided in the draft package insert and IFU for cleaning and sterilization of non-sterile instrumentation, respectively. The parameters are in accordance with tables 4 and/or 5 of ANSI/AAMI ST79. See Sterilization section below for details.

The following parameters are recommended for resterilization of metal implants: steam heat using a gravity

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displacement cycle at 121° C (250° F) for 30 minutes (minimum), allowing 15 minutes (minimum) of drying time, and steam heat using a gravity displacement cycle at 132° C (270° F) for 15 minutes (minimum), allowing 15 minutes (minimum) of drying time. For instruments a pre-vacuum cycle at 132° C (270° F) for 4 minutes (minimum), allowing 30 minutes (minimum) of drying time, is recommended. These are the same as for other Zimmer systems.

The surgical technique appears acceptable. It provides all detailed aspects of the surgery with device specific instrumentation. It includes schematics and photos in conjunction with the text.

Reviewer Comment: *In their 2/27/13 email response to our interactive review deficiencies discussed via phone (and email) on 2/22/13 the sponsor provided an updated package insert that included the above referenced MR statements. The labeling is acceptable.*

A revised 510(k) Summary was provided via email on 2/28/13. It includes requested revisions such as a complete device description section (as per the RTA checklist and 510(k) Summary checklist [per 21 CFR 807.92]), corrections to the product code and regulation/classification names, and replacement of the word "semi-constrained" with "constrained". The 510(k) Summary is now acceptable.

In addition, in the 2/27/12 email the sponsor revised the following sections of the submission by replacing the term "semi-constrained" with "constrained", as requested:

- *original K123862 submission page 16 – see page 1 of Attachment 2*
- *original K123862 submission page 56 – see page 1 of Attachment 4*
- *original K123862 submission page 61 – see page 1 of Attachment 5*
- *original K123862 submission page 74 – see page 14 of Attachment 5*
- *RTA Response page 4 – see page 2 of Attachment 6*
- *RTA Response page 27 – see page 9 of Attachment 7*
- *original K123862 submission page 57 – see page 2 of Attachment 4*

VII. Sterilization/Shelf Life/Reuse

All implant components are provided sterile. The metallic humeral component, ulnar component, and humeral screws are sterilized by gamma irradiation. The articulation kit (humeral bearing-A, 2 ulnar bearings –B, and an axle pin) which contains highly-crosslinked Vitamin E UHMWPE components is sterilized by ethylene oxide. Some instruments are also provided sterile.

Metallic implant components provided sterile by radiation:
Method: gamma radiation from a Co 60 source
Dosage: 25 - 37 kGy (2.5 – 3.7 Mrads)
Sterility Assurance Level: 10^{-6}
Validation Method: ANSI/AAMI/ISO 11137-1: 2006 (*Sterilization of health care products. Part 1. Radiation. Requirements for development, validation and routine control of a sterilization process for medical Devices.)*, 11137-2: 2006 *(Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose)*, and AAMI TIR 33: 2005, *(Sterilization of health care products – Radiation Substantiation of a selected sterilization dose – Method VDmax)*.
Pyrogenicity: Components will *not* be labeled as nonpyrogenic or pyrogen free. Per USP XXIII (161), requirements for specified endotoxin levels do not apply to orthopedic implants.

Articulation kit (1 Vivacit-E humeral bearing-A and 2 Vivacit-E ulnar bearings-B and an axle-pin) provided sterile by EO
Method: Ethylene Oxide
Validation: AAMI/ISO 11135-1: 2007 (*Sterilization of health care products – Ethylene Oxide Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*).
SAL: 10^{-6}
Pyrogenicity: Components will *not* be labeled as pyrogen free.

Residual Levels: The maximum levels of residuals of EO and ethylene chlorohydrin that remain on the device do not exceed the maximum allowable limits described in AAMI/ISO 10993-7: 2008 (*Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals*) for permanent contact devices. The maximum allowable levels are as follows:

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- The average daily dose of EO to patient shall not exceed 0.1mg/d. In addition the maximum EO dose shall not exceed 4mg in the first 24 hours; 60mg in the first 30 days; and 2.5 grams in a lifetime.
- The average daily dose of ECH to patient shall not exceed 0.4mg/d. In addition the maximum ECH dose shall not exceed 9mg in the first 24 hours; 60mg in the first 30 days; and 10 grams in a lifetime.

The sponsor provided EO residuals testing results via an interactive review email sent/received on 2/14/13. The results are below the maximum allowable limits noted above for each specified time point.

Class II accessories provided sterile
The following accessories listed in Section 11a (Device Description) of the submission are provided sterile and are intended to be used during only one surgery (single use) and are not intended to be end-user sterilized.

Catalog Number	Description	Sterilization Method	Radiation Dose	Validation Method	SAL
00-8401-088-00	Humeral Screw Installation Driver Bit	Gamma Irradiation	(b)(4)	AAMI TIR33, VD_{MAX}	10^{-6} or better
00-8401-080-00	Torque-Limiting Humeral Screw Driver	Gamma Irradiation		AAMI 11137-2, VD_{MAX}	10^{-6} or better

Table 1. Class II Accessories to the Implant provided sterile

Packaging:
Humeral Stem -
(b)(4)

Ulnar Stem -
(b)(4)

Articulation Kit -
(b)(4)

Humeral Screw Kit -
(b)(4)

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- (b)(4)

The above listed materials are identical to those currently in use for Zimmer sterile implant packages with the only exception being that the configuration of the interior components correspond to the particular product being packaged.

The Class II Accessories to the Implant (listed in Table 1, above) that are provided sterile are packaged as follows:

Humeral Screw Installation Driver Bit -
(b)(4)

Torque-Limiting Humeral Screw Driver -
(b)(4)

The above listed materials are identical to those currently in use for other similar Zimmer sterile implant packages with the only exception being that the configuration of the interior components correspond to the particular product being packaged.

Recommended and validated sterilization parameters for end users of reusable class II accessories (instruments) provided non-sterile:
Method: moist heat (steam)
Validation: AAMI/ANSI/ISO 17665-1:2006 *Sterilization of Health Care Products - Moist Heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.* Half cycle method (Overkill method).
Sterility Assurance Level: 10^{-6}
Cycle: dynamic air removal (pre-vacuum) for 4 minutes at 132° C with 30 minutes minimum dry time, using recommended sterilization wraps.

Parameters conform to those in Table 5 of AAMI ST79: 2010.

Shelf-Life:
The shelf life of the packaging for the Zimmer Nexel Total Elbow humeral component, ulnar component and humeral screws (note: the "humeral screws" are also referred to as the "humeral screw kit") is 10 years. The shelf life of the articulation kit (the humeral bearing-A, humeral bearings-B and the axle pin) is 5 years. This testing was performed according to ASTM F1980 (*Standard Guide for Accelerated Aging for Sterile Medical Device Packages*) and ANSI/AAMI/ISO 11607: 2006 (*Packaging for Terminally Sterilized Medical Devices*). The packaging materials demonstrate no degradation over time and the shelf life test data assures sterile packaging integrity.

Reviewer Comment: *Sterilization/packaging is acceptable as currently presented, and is identical to earlier predicate submissions of theirs. Resterilization of UHMWPE device implants is specifically not recommended.*

VIII. Biocompatibility
The device materials, CoCrMo alloy and titanium alloy, have a long (~40 years) and successful history in orthopedic total joint replacement. The materials also conform to recognized material standards. According to

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FDA reviewer Michael Kasser, Ph.D., the Vivacit-E UHMWPE (Vitamin E [α-tocopherol] stabilized, highly crosslinked ultra-high molecular weight polyethylene), which is contained within the Zimmer Vitamin E Stabilized HXPE Material Master File (FDA Ref: MAF-1868) has been previously cleared for use in other Zimmer devices and does not present a biocompatibility concern.

On page 15 of the sponsor's 1/17/13 RTA response it is noted that all of the class II accessories (instruments) are external communicating devices contacting tissue/bone with limited exposure (less than 24 hour duration), according to definitions presented in Section 5 of ISO 10993-1.

No information on colorants was provided in the original submission. In an interactive review teleconference (and email) with the sponsor on 2/22/13 the sponsor was asked to either identify any colorants (if any) and the predicate device systems that utilize these colorants, or provide biocompatibility information. In their email response dated and received on 2/27/13 the sponsor identified that two colorants were used with the subject instrumentation. They also identified two predicate device systems that have utilized these same colorants in similar instrument components (K040593, K933785). The colorants were not identified by name but since they are just used in instrument handles and have been used for 9 and 20 years, respectively (and one is disposable, single-use only), no additional information will be asked for at this time. Therefore, the response is acceptable; and no further information is required to 'grandfather' in these colorants. The sponsor was notified, however, that in the future any new colorants will need biocompatibility information provided in the 510(k) of the associated device system.

Reviewer Comment: *No additional biocompatibility information is needed.*

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

None.

Reviewer Comment: *Electromagnetic compatibility data is typically not provided in orthopedic 510(k) submissions. Electrical and thermal safety issues are not relevant (typically) to orthopedic devices. The sponsor's package insert, as amended in the sponsor's 2/27/13 email response, includes appropriate MR language. Mechanical safety issues are addressed in the following section on performance testing.*

X. Performance Testing – Bench

The Nexel Total Elbow has been evaluated in comparison to its predecessor and predicate device system, the Coonrad/Morrey Total Elbow. The following table identifies the types of testing conducted by the sponsor. Test results demonstrate that the subject device performed as well as or better than the predicate device for each test. This is as expected due to the very similar nature of the device designs. The subject device incorporates iterative design changes from the predicate, implementing improvements in some areas (e g., humeral stem fatigue strength, wear, durability) and maintaining equivalence in others (ulnar stem fatigue strength). Detailed protocols and test reports are provided in Section 18 of the submission.

Test	Test Results: Proposed Device: The Zimmer Nexel Total Elbow	Test Results: Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Fatigue Testing: Humeral Stem (Plasma Spray Region)	Five Zimmer Nexel Total Elbow humeral stems achieved (b)(4) load cycles at (b)(without fracture.	The predicate device humeral component was fatigue tested at various load levels, and the fatigue strength at (b)(4) cycles was determined to be (b)
Fatigue Testing: Ulnar Stem (Mid-Stem Region)	Five Zimmer Nexel Total Elbow ulnar stems achieved (b)(4) load cycles in the mid-stem region at a load of (b)(without fracture.	The predicate device ulnar component was fatigue tested at various load levels, and the fatigue strength at (b)(4) load cycles in the mid-stem region was determined to be (b)(

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Fatigue Testing: Ulnar Stem (Plasma Spray Region)	Five Zimmer Nexel Total Elbow ulnar stems achieved (b)(4) load cycles in the plasma spray region at a load of (b)(without fracture.	The predicate device ulnar component was fatigue tested at various load levels, and the fatigue strength at (b)(4) load cycles in the plasma spray region was determined to be (b)(
Wear Testing	The Zimmer Nexel Total Elbow mean gravimetric wear rate (b)(4) at (b)(4) load cycles) was (b) less than that of the predicate.	The predicate device mean gravimetric wear rate was (b)(4) load cycles.
Durability Testing	The Zimmer Nexel Total Elbow device achieved (b)(4) outs at an equivalent of (b)(weight-in-hand.	The run out load for the predicate device was found to be equivalent to (b)(4) weight-in-hand.
Modular Connection Fatigue Testing	The median fatigue strength of the non-articulating, mechanically locked, modular Zimmer Nexel Total Elbow implant components was no less than (b)(4	Not Applicable: The Zimmer Coonrad/Morrey Total Elbow does not have non-articulating, mechanically-locked, modular implant components comparable to those of the proposed device.

The testing confirms that the Nexel Total Elbow is capable of withstanding expected in-vivo loading and is substantially equivalent to predicate elbow systems.

The sponsor also performed bench testing to support a claim regarding delamination resistance of the Vivacit-E UHMWPE bearing material. Michael Kasser, Ph.D., polymers expert in DOD, acknowledged that this claim was similar to previous claims made for this material (in other joints) and appeared acceptable as provided. Casey Hanley, Ph.D., reviewer in JFOB has reviewed similar Zimmer claims for this material and also confirmed that it appeared acceptable.

The claim reads as follows:

Proposed Claim
Vivacit-E Vitamin E Highly Crosslinked Polyethylene exhibits improved delamination resistance compared to conventional polyethylene under aged conditions (per ASTM F2003). The results of *in vitro* delamination tests have not been shown to correlate with clinical delamination mechanisms.

Evidence to Support Claim

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

Testing supports this claim. See page 207 in Section 18 and the test report 26_ZRR_WA_2580_12 in Section 18b, for details.

Reviewer Comment: *The Nexel Total Elbow has been evaluated for humeral and ulnar stem fatigue strength, wear resistance, durability, and modular connection fatigue strength. The testing demonstrates that the Nexel Total Elbow is capable of withstanding expected in-vivo loading and is substantially equivalent to predicate elbow systems. In addition, testing supports the sponsor's proposed claim regarding delamination resistance. Performance testing is adequate. No additional testing is necessary.*

XI. Substantial Equivalence Discussion

The materials, design, sizes, indications, intended use, sterilization, and packaging, for the subject device are similar and/or identical to legally marketed predicate devices. The sponsor provided, via interactive review, additional information including EtO residual testing results, details on colorants used in their instrumentation, updated labeling to include appropriate MR statements, additional discussion regarding the differences in range of motion between their device and the predicate device, edits to all relevant parts of the submission to replace the device descriptive term "semi-constrained" with the appropriate term "constrained", and revisions to the 510(k) Summary.

The sponsor has provided adequate characterization in terms of device design, sizes, material, intended used and testing to demonstrate that the subject device components are equivalent to marketed predicate devices. **Therefore, I recommend SE.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of *Safety Or Effectiveness?*			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

Questions 2, 4, and 6 are not applicable.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough: *Testing, to demonstrate that the design, strength, and compatibility of the subject components are adequate to perform as intended and are comparable to predicate devices, and support proposed wear claims, needs to be provided.*

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed: *Bench test data (fatigue, wear, modular connections) to demonstrate that the subject device compares favorably to predicate devices. Testing also needs to support proposed claims regarding delamination resistance of the Vivacit-E UHMWPE.*

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *Bench test data provided in this submission, including fatigue strength, wear, durability, and modular connection testing demonstrated that the subject device performs as well as or better than predicate devices. Testing also supports proposed claims regarding delamination resistance of the Vivacit-E UHMWPE.*

XII. Deficiencies

None.

XIII. Contact History

12/28/12 – Sponsor was notified via email of the RTAX (Refuse to Accept – transition period) status of their submission. A copy of the RTA checklist was provided, that included comments on those items noted to be deficient. See submission file for details.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

1/15/13 – Phone conversation with Ms. Joanna Surma discussing the timeline for Zimmer's submittal of EO residual data for FDA review. See submission file (1/16/13 email from Ms. Surma and attachment with RTA response dated 1/17/13) for details.

1/16/13 – Sponsor responded via email to the deficiencies cited in the RTA checklist. All items were adequately addressed. See amended submission file for details.

2/11/13 – Sent an email to the sponsor requesting the EO residual test results.

2/13/13 – Automated email sent to sponsor notifying them that a substantive review of their submission had been completed and that FDA would proceed interactively with them to resolve any remaining deficiencies.

2/14/13 – Sponsor provided EO residual test results via email.

2/22/13 – Phone conversation with the Ms. Surma and Jason Heckaman to discuss outstanding issues to be addressed interactively. General issues were forwarded to the sponsor via email prior to the telecon. They included the following:

- Need for MR statement in the package insert
- Identify any color additives that may be included in any device instrumentation.
- Update 510(k Summary to include correct regulation/classification name, procode name. Semi-constrained versus constrained – revise.
    - Classification: 21 CFR 888.3150 – Elbow joint metal/polymer constrained cemented prosthesis.
    - Product Code: JDC – Prosthesis, Elbow, Constrained, Cemented
- Nitriding location: on interior surface of ulnar eye or just outer surface, or both?
- Variations in ROM from predicate; discussion of differences and the effect, if any.

2/27/13 - Sponsor responded via email to the requests made during the 2/22/13 teleconference. They provided all the requested information. See appropriate sections of this review memo for details about the responses.

2/28/13 – Sponsor provided an updated 510(k) Summary via email. See Reviewer Comment in the Labeling section of this review memo for details.

All email correspondence and attachments have been added to the submission file. See submission file, as amended, for details.

XIV. Recommendation

Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code(s): JDC

I recommend this submission, as revised by emails submitted during interactive review, be found SE. An SE Letter should be sent to the sponsor.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Peter G. Allen 2013.03.08 16:09:20 -05'00' FDA
Branch Chief Sign-Off	
Division Sign-Off	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Allen, Peter

From: Joanna L. Surma <Joanna.Surma@zimmer.com>
Sent: Thursday, February 28, 2013 10:04 AM
To: Allen, Peter
Subject: RE: K123862 Review will Proceed via Interactive Review
Attachments: Attachment 2 - 05. 510(k) Summary.pdf

Importance: High

Hi Pete,

I noticed that I provided the wrong Attachment 2. Please replace the one previously sent with this one.

Thanks,
Joanna

Joanna L. Surma - MS, RAC
Associate Project Manager
Regulatory Affairs
Zimmer, Inc.
(o) 574.371.1642
(c) 574.527.2361

From: Joanna L. Surma
Sent: Wednesday, February 27, 2013 1:48 PM
To: 'Allen, Peter'
Subject: K123862 Review will Proceed via Interactive Review
Importance: High

Hi Pete,

Thanks for the call last week. Below, are the clarifications requested.

1. MR Statements in the Package Insert: See Attachment 1 (page 4) for a revision of the Nexel Total Elbow package insert.

2. List of colorant additives in non-metallic instrumentation along with part numbers and K-numbers of legally marketed devices with the same colorant additives:

Non-Metallic Part Number	Description	Non-Metallic Material	Color Additive?	Part Number and K-Number of Legally Marketed Device with the Same Color Additive
00-8401-028-00	Ulnar Stem Inserter	Radel	none	NA
00-8401-088-00	Humeral Screw Installation Driver Bit	LDPE	none	NA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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zimmer

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary of Safety and Effectiveness

Sponsor:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person:

Joanna L. Surma
Associate Project Manager, Regulatory Affairs
Telephone: (574) 371-1642
Fax: (574) 372-4605

Date:

13 December 2012

Trade Name:

Zimmer Nexel Total Elbow

Common Name:

Total Elbow Prosthesis

Classification

21 CFR § 888.3150
Elbow joint metal/polymer constrained cemented prosthesis

Product Code:

JDC – Prosthesis, Elbow, Constrained, Cemented

Predicate Device:

Coonrad/Morrey Total Elbow, manufactured by Zimmer, K001989, cleared 25 July 2000

Coonrad/Morrey Total Elbow, manufactured by Zimmer, K053189, cleared 9 December 2005

Device Description:

The Zimmer Nexel total Elbow is a total elbow prosthesis designed for use with bone cement. It is available in multiple sizes and in right and left configurations.

How the Device Functions: The Zimmer Nexel Total Elbow is an implant designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a constrained device assembly and consists of the following components: humeral component, ulnar component, humeral bearing-A, ulnar bearings-B, axle pin and humeral screws.

The Following Scientific Concepts, Design Features and Physical Properties form the Basis for the Zimmer Nexel Total Elbow: The humeral component has a humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal, an anterior flange designed to accept a

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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bone graft and limit torsional and posterior migration, a humeral yoke with rounded corners to avoid the creation of stress risers within the medial and lateral humeral supracondylar columns, and plasma spray region to enhance fixation to bone cement within the medullary canal, and to improve fatigue strength. The ulnar component has an ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal, an ulnar eye that is both highly polished and nitrogen-enriched to limit wear of the apposing polymer bearings, and plasma spray region to enhance fixation to bone cement within the medullary canal. Bearings A and B are designed to broadly distribute joint reaction forces.

Materials Used: The humeral and ulnar components are made of a titanium alloy, the bearings A and B are made of Vitamin E highly cross-linked polyethylene, and the humeral screws and axle pin are made of a cobalt-chromium-molybdenum alloy.

Comparison to the Predicate: The proposed device (Zimmer Nexel Total Elbow) and the predicate device (Coonrad/Morrey Total Elbow) have the same intended use and similar indications for use. The proposed device humeral and ulnar components are very similar in terms of materials used and design/dimensions to the predicate device humeral and ulnar components. The primary differences between the proposed and predicate devices are that the proposed device bearing components are made of Vitamin E highly cross-linked polyethylene (the predicate device bearing components are made of ultra-high molecular-weight polyethylene), and the proposed device has bearings that articulate on both the outer and inner diameters of the ulnar eye (the predicate device has bearings that articulate on the inner diameter of the ulnar eye). Additionally, the proposed device uses screws and a 1-part axle pin to fix the bearings in place, while the predicate device uses a 2-part (snap-fit) axle pin.

Intended Use:

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

Caution: This device is intended for cemented use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary of Safety and Effectiveness – Zimmer Nexel Total Elbow

Comparison to Predicate Device:

The Zimmer Nexel Total Elbow is substantially equivalent to the predicate device in terms of form and function. The Zimmer Nexel Total Elbow and the predicate device share similar intended uses and indications for use.

Performance Data:

Non-Clinical Performance Testing Conducted:

- Stem Fatigue Testing
- Wear Testing
- Durability Testing
- Modular Connection Fatigue Testing

Non-Clinical Performance Testing Conclusions:

Non-clinical testing demonstrated that the New Zimmer Total Elbow meets performance requirements as defined by Design Control activities and is substantially equivalent to the predicate device in terms of safety and efficacy.

In this case, clinical data and conclusions were not needed to demonstrate substantial equivalence.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Allen, Peter

From: Joanna L. Surma <Joanna.Surma@zimmer.com>
Sent: Wednesday, February 27, 2013 1:48 PM
To: Allen, Peter
Subject: K123862 Review will Proceed via Interactive Review
Attachments: Attachment 1 - 13c. Package Insert.pdf; Attachment 3 - 18b.7 ZRR_WA_2476_11.pdf; Attachment 2 - 05. 510(k) Summary.pdf; Attachment 5 - Device Description - .pdf; Attachment 6 - RTA Response - 02 - Zimmer Responses.pdf; Attachment 7 - RTA Response - 12a. Substantial Equivalence Discussion.pdf; Attachment 4 - Executive Summary.pdf

Importance: High

Hi Pete,

Thanks for the call last week. Below, are the clarifications requested.

1. MR Statements in the Package Insert: See Attachment 1 (page 4) for a revision of the Nexel Total Elbow package insert.

2. List of colorant additives in non-metallic instrumentation along with part numbers and K-numbers of legally marketed devices with the same colorant additives:

Non-Metallic Part Number	Description	Non-Metallic Material	Color Additive?	Part Number and K-Number of Legally Marketed Device with the Same Color Additive
00-8401-028-00	Ulnar Stem Inserter	Radel	none	NA
00-8401-088-00	Humeral Screw Installation Driver Bit	LDPE	none	NA
00-8401-089-00	Humeral Screw Removal Driver	Silicone	Yes	00-2360-087-00 K040593
00-8401-080-00	Torque-Limiting Humeral Screw Driver	Ultem	Yes	00-5971-050-09 K933785

3. Update 510(k) summary to include correct regulation/classification name and product code name: See Attachment 2 for an updated 510(k) summary. revised again on 2/28/13 - PGA

4. Nitriding location: On all surfaces of ulnar eye. Discussion point closed during phone call.

5. Discussion of ROM:

   The Nexel Total Elbow's allowable flexion arc from (b)(4) and varus/valgus laxity of (b)(4) comply well with the 0-146° flexion arc and +/-3°-5° range of varus/valgus angulation of a normal, healthy elbow reported in the referenced studies summarized in Zimmer's *BIOMECHANICS RATIONALE FOR THE LOADING OF TOTAL ELBOW PROSTHESIS DURING IN VITRO SIMULATIONS* document (included in the initial K123862 submission and also provided here as Attachment 3). While the predicate C/M implant assembly allows (b)(4) (depending on the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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size configuration) flexion and up to (b)(of v/v laxity, the normal elbow doesn't allow (due to soft and hard tissue limitations) this much flexion and functions normally within the (b)(4 v/v angulation range provided by both the Nexel and the C/M.

The Nexel Total Elbow was designed to provide at least as much of the necessary flexion and v/v laxity as required of a normal, healthy elbow while maximizing the thickness and optimizing the location and form of the Vitamin-E UHMWPE Bearings to provide improved wear resistance and longer-term load-bearing capability as compared to the predicate device. Thus, any flexion and v/v angulation deemed unnecessary for a full healthy elbow range of motion was traded for optimization of device performance; this is further substantiated by the results of the head-to-head Wear and Durability tests reported in the initial K123862 submission, wherein both (Nexel and predicate) devices were subjected to high-loading over large flexion arcs with induced v/v angulation to simulate clinically-relevant, yet aggressive, long-term use in-vivo.

6. Although, we believe the Nexel Total Elbow is a semi-constrained device in the engineering sense (that it is not a rigid hinge-like device fully-constrained to only rotation about a single axis; that it, in fact, allows for an additional range of varus/valgus motion about that hinge), we agree that this engineering understanding of "semi-constrained" still falls under the FDA definition of "constrained" and have changed the following submission pages accordingly:
   - Initial K123862 submission page 16 – see page 1 of Attachment 2
   - Initial K123862 submission page 56 – see page 1 of Attachment 4
   - Initial K123862 submission page 61 – see page 1 of Attachment 5
   - Initial K123862 submission page 74 – see page 14 of Attachment 5
   - RTA Response page 4 – see page 2 of Attachment 6
   - RTA Response page 27 – see page 9 of Attachment 7
   - Initial K123862 submission page 57 – see page 2 of Attachment 4

Please let me know if you require any further clarifications.

Sincerely,
Joanna

Joanna L. Surma - MS, RAC
Associate Project Manager
Regulatory Affairs
Zimmer, Inc.
(o) 574.371.1642
(c) 574.527.2361

From: Allen, Peter [mailto:Peter.Allen@fda.hhs.gov]
Sent: Friday, February 22, 2013 1:42 PM
To: Joanna L. Surma
Subject: RE: K123862 review will proceed via interactive review

Joanna,

Very generally, here are the issues:

- Need for MR statement in the package insert
- Colorant additives that may be included in any instrumentation
- Update 510(k Summary to include correct regulation/classification name, procode name. Semi-constrained versus constrained – revise.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- Classification: 21 CFR 888.3150 – Elbow joint metal/polymer constrained cemented prosthesis.
- *Product Code: JDC – Prosthesis, Elbow, Constrained, Cemented*

- Nitriding location: on interior surface of ulnar eye or just outer surface, or both?
- Variations in ROM from predicate; discussion of differences and the effect, if any.

Pete

From: Joanna L. Surma [mailto:Joanna.Surma@zimmer.com]
Sent: Friday, February 22, 2013 10:28 AM
To: Allen, Peter
Subject: RE: K123862 review will proceed via interactive review

3pm EST should work for me. Could you please let me know the topics of discussion, so I can make sure to have the appropriate subject-matter experts in the conference?

Thanks,
Joanna

Joanna L. Surma - MS, RAC
Associate Project Manager
Regulatory Affairs
Zimmer, Inc.
(o) 574.371.1642
(c) 574.527.2361

From: Allen, Peter [mailto:Peter.Allen@fda.hhs.gov]
Sent: Friday, February 22, 2013 10:25 AM
To: Joanna L. Surma
Subject: RE: K123862 review will proceed via interactive review

Joanna,

I have a couple of items I'd like for you to address for me before I SE this submission. I will attempt to call you later this afternoon to discuss (~3pm) if my schedule permits (I'm in meetings most of the day today), otherwise I will send an email to you and we can discuss next week.

Pete Allen
301-796-6402

From: Joanna L. Surma [mailto:Joanna.Surma@zimmer.com]
Sent: Monday, February 18, 2013 6:09 PM
To: Allen, Peter
Subject: RE: K123862 review will proceed via interactive review

Hello Mr. Allen,

Please let me know how you'd like to proceed with the interactive review.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Thanks, and I look forward to hearing from you soon,

Joanna

Joanna L. Surma - MS, RAC
Associate Project Manager
Regulatory Affairs
Zimmer, Inc.
(o) 574.371.1642
(c) 574.527.2361

From: Peter Allen [mailto:peter.allen@fda.hhs.gov]
Sent: Wednesday, February 13, 2013 3:52 PM
To: Joanna L. Surma; Jason Heckaman
Cc: Peter Allen
Subject: K123862 review will proceed via interactive review

February 13, 2013 **Substantive Review Notification - Proceed Interactively**

FDA has completed a substantive review of your submission K123862 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Attachment 1
2/27/13 email
- Package Insert -

Bar code 87-6204-077-99	Rx only	Rev. – September 2012 © 2012, Zimmer, Inc.

ZIMMER® NEXEL™ TOTAL ELBOW

zimmer	Zimmer, Inc 1800 West Center Street Warsaw, Indiana 46580 USA 1-800-348-2759 (US only) +1-574-372-4999	EC REP Zimmer U.K. Ltd. 9 Lancaster Place South Marston Park Swindon, SN3 4FP, UK	CE 0086

English

The CE mark is valid only if it is also printed on the product label

ZIMMER® NEXEL™ TOTAL ELBOW

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Before using a product placed on the market by Zimmer, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., product literature, written surgical technique). Zimmer is not liable for complications arising from the use of this device outside of its indicated uses, not aligned with the surgical technique, product selection or similar matters outside the control of Zimmer.

DESCRIPTION

This device is a total elbow prosthesis designed for use with bone cement. It is available in sizes 4, 5 and 6, in left and right configurations. The ulnar and humeral implant components are manufactured from *Tivanium*® Ti-6Al-4V alloy. The ulnar implant component has a porous coating of Ti-6Al-4V plasma spray and is curved to facilitate implantation. The humeral implant component has a porous coating of Ti-6Al-4V plasma spray and has an anterior flange to accommodate a bone graft. The linkage pin and screws are manufactured from *Zimaloy*® Co-Cr-Mo alloy. Vitamin E highly cross-linked ultra-high molecular weight polyethylene (*Vivacit-E*®) bearings prevent metal-to-metal articulating contact.

INDICATIONS

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

CAUTION: This device is intended for cemented use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

CONTRAINDICATIONS

Use of the *Zimmer Nexel* Total Elbow is contraindicated in patients with

- *Currently active*, or history of repeated, local infection at the surgical site
- Paralysis or dysfunctional neuropathy involving the elbow joint
- Significant ipsilateral hand dysfunction
- Excessive scarring of the skin or soft tissue that could prevent adequate soft tissue coverage
- Daily activities that would subject the device to significant stress (i.e., heavy labor, torsional stress, and/or competitive sports)

Relative contraindications include

- Distant foci of infection (e.g. genitourinary, pulmonary, skin [chronic lesions or ulcerations] or other sites). In cases of distant infection the foci of infection should be treated prior to, during and after surgery.
- Ancient prior sepsis

WARNINGS

- This device is for single patient use only. Do not reuse. Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.
- To properly implant this device the surgical technique should be consulted and carefully followed.
- Cementing technique is extremely important. The medullary canal should be copiously irrigated to remove blood, fat, and bone debris, and then thoroughly dried. A cement delivery system should be used to cement the humeral and ulnar implant components.
- A snug mechanical fit of the implant within the humeral and ulnar medullary canals may help minimize loosening of the implant components.
- The amount of bone removed from the ulna should be sufficient to permit full elbow motion on the operating table when the appropriate provisional prosthesis is fully inserted. The surgeon should check for full range of elbow motion at appropriate times during surgery.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

PRECAUTIONS

- Proper handling of this implant is important. Contouring (bending) of the humeral or ulnar stems should be avoided. Any alteration may produce defects that could become focal points for excessive stresses leading to implant failure.
- To prevent late infection of total joint implants, many surgeons advise the use of antibiotic prophylaxis before and after dental manipulation, endoscopic examinations and other minor surgical procedures.
- Patients with significant lower extremity disability who require walking aids are less amenable to total elbow arthroplasty than patients with advanced and predominately upper extremity involvement.
- The *Zimmer Nexel* Total Elbow has not been evaluated for safety and compatibility in the MR environment.
- The *Zimmer Nexel* Total Elbow has not been evaluated for heating or migration in the MR environment.

ADVERSE EFFECTS

The following adverse effects have been reported:

- Early or late component loosening
- Implant failure or fracture
- Infection
- Nerve injury
- Triceps avulsion
- Cortical perforations and fractures
- Adverse tissue response and inflammatory reaction to the implant material or wear debris, including metal sensitivity
- Osteolysis and/or loosening due to wear debris

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

STERILITY

The *Zimmer Nexel* Total Elbow implants are provided sterile (the humeral and ulnar implant components, and the humeral screws are sterilized by gamma irradiation, indicated by the STERILE R symbol on the labeling; and, the articulation kit – including the bearings and the axle pin – is sterilized by ethylene oxide, indicated by the STERILE EO symbol on the labeling) and remain sterile until the expiration date displayed on the package, as long as the package integrity has not been violated. Inspect each package prior to use and do not use the implant component if any seal or cavity is damaged or breached or if the expiration date has been exceeded. Once opened, the implant component must be used, discarded or re-sterilized.

STERILIZATION INSTRUCTIONS

These sterilization instructions are consistent with ANSI/AAMI/ISO standards and guidelines. They should be used for sterile items that were opened but unused.

- Do not reuse implants.
- In the event of inadvertent loss of sterility while preparing for surgery, all metal implant components may be re-sterilized only once for immediate use. This is subject to the exceptions listed below:

  DO NOT RE-STERILIZE

  - Implant components that have been contaminated with body fluids or biologic debris, or that have been previously implanted.
  - Implant components with a packaging expiration date that has been exceeded.
  - Implant components containing *Vivacit-E* polyethylene.
  - Any plastic, foam or polyethylene.
- Do not use the original plastic cavities or lids for re-sterilization. Single implant components should be packaged in a medical grade sterilization pouch or wrap that conforms to the recommended specifications for steam sterilization provided in the table under *Recommended Sterilization/Re-sterilization Specifications* below. Ensure that the pouch or wrap is large enough to contain the implant component without stressing its seals or tearing.
- Implant components must be disassembled and sterilized separately to minimize potential bio-burden buildup in the dead space and expansion/contraction stresses.
- Rinse implant components, paying special attention to porous coatings, to remove lint or other non-biologic debris using USP (United States Pharmacopeia) purified water.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Recommended Sterilization/Re-sterilization Specifications
Follow the sterilizer manufacturer's instructions for loading patterns and selection of sterilization parameters. Drying times vary according to load size and should be increased for larger loads.

For Single, All Metal Implants

Steam Sterilization

Type	Temperature	Exposure Time	Minimum Dry Time
Gravity Displacement	121°C (250°F)	30 minutes	15 minutes
Gravity Displacement	132°C (270°F)	15 minutes	
UK Pre-vacuum/Pulsating Vacuum[1]	134°C (273°F)	3 minutes	
Pre-vacuum/Pulsating Vacuum	132°C (270°F)	4 minutes	

[1] This cycle is not for use in the United States

Please contact Zimmer at the following number if you have additional questions. In the USA, call 1-800-348-2759. For calls outside the USA, call the local international access code +1-574-267-6131.

STERILIZATION PRECAUTIONS

- Aggressive cleaning with detergents and brushes may damage special features of the implants, such as porous coatings. Also, certain detergents may be difficult to rinse off polymer items, especially those made of silicone rubber.
- Items made from titanium and titanium alloys can form oxide layers from steam boiler treatment chemicals or detergent residues. While these oxides are biocompatible, they can obliterate identification etchings and stampings.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PATIENT COUNSELING INFORMATION

Complications and/or failure of prosthetic implants are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or with patients who fail to follow through with the required rehabilitation program. Physical activity can result in loosening, wear, and/or fracture of the implant. The prospective implant patient must be counseled about the capabilities of the implant and the impact it will have on his or her lifestyle. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities, and about the possibility that the implant or its components may wear out, fail or need to be replaced. The implant may not last the rest of the patient's life, or any particular length of time. Because prosthetic implants are not as strong, reliable, or durable as natural, healthy tissues/bones, all such devices may need to be replaced at some point.

Note: The prosthesis will not restore function to the level expected with a normal healthy joint, and has functional limitations. Excessive muscular activity such as pounding and or carrying excessive loads must be avoided or restricted. The patient must not lift more than one pound (~0.5 kg) during the first three postoperative months; and, thereafter, not more than five pounds (~2.25 kg) with the operated arm. In addition, the risks and complications listed under ADVERSE EFFECTS must be explained to and discussed with the patient.

CAUTION: This device is intended for cemented use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 2

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary of Safety and Effectiveness

Sponsor:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person:

Joanna L. Surma
Associate Project Manager, Regulatory Affairs
Telephone: (574) 371-1642
Fax: (574) 372-4605

Date:

13 December 2012

Trade Name:

Zimmer Nexel Total Elbow

Common Name:

Total Elbow Prosthesis

Classification

21 CFR § 888.3150
Elbow joint metal/polymer constrained cemented prosthesis

Product Code:

JDC – Prosthesis, Elbow, Constrained, Cemented

Predicate Device:

Coonrad/Morrey Total Elbow, manufactured by Zimmer, K001989, cleared 25 July 2000

Coonrad/Morrey Total Elbow, manufactured by Zimmer, K053189, cleared 9 December 2005

Device Description:

The Zimmer Nexel total Elbow is a total elbow prosthesis designed for use with bone cement. It is available in multiple sizes and in right and left configurations.

How the Device Functions: The Zimmer Nexel Total Elbow is an implant designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a semi-constrained device assembly and consists of the following components: humeral component, ulnar component, humeral bearing-A, ulnar bearings-B, axle pin and humeral screws.

The Following Scientific Concepts, Design Features and Physical Properties form the Basis for the Zimmer Nexel Total Elbow: The humeral component has a humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal, an anterior flange designed to accept a

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bone graft and limit torsional and posterior migration, a humeral yoke with rounded corners to avoid the creation of stress risers within the medial and lateral humeral supracondylar columns, and plasma spray region to enhance fixation to bone cement within the medullary canal, and to improve fatigue strength. The ulnar component has an ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal, an ulnar eye that is both highly polished and nitrogen-enriched to limit wear of the apposing polymer bearings, and plasma spray region to enhance fixation to bone cement within the medullary canal. Bearings A and B are designed to broadly distribute joint reaction forces.

Materials Used: The humeral and ulnar components are made of a titanium alloy, the bearings A and B are made of Vitamin E highly cross-linked polyethylene, and the humeral screws and axle pin are made of a cobalt-chromium-molybdenum alloy.

Comparison to the Predicate: The proposed device (Zimmer Nexel Total Elbow) and the predicate device (Coonrad/Morrey Total Elbow) have the same intended use and similar indications for use. The proposed device humeral and ulnar components are very similar in terms of materials used and design/dimensions to the predicate device humeral and ulnar components. The primary differences between the proposed and predicate devices are that the proposed device bearing components are made of Vitamin E highly cross-linked polyethylene (the predicate device bearing components are made of ultra-high molecular-weight polyethylene), and the proposed device has bearings that articulate on both the outer and inner diameters of the ulnar eye (the predicate device has bearings that articulate on the inner diameter of the ulnar eye). Additionally, the proposed device uses screws and a 1-part axle pin to fix the bearings in place, while the predicate device uses a 2-part (snap-fit) axle pin.

Intended Use:
Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

Caution: This device is intended for cemented use only.

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510(k) Summary of Safety and Effectiveness – Zimmer Nexel Total Elbow

Comparison to Predicate Device:

The Zimmer Nexel Total Elbow is substantially equivalent to the predicate device in terms of form and function. The Zimmer Nexel Total Elbow and the predicate device share similar intended uses and indications for use.

Performance Data:

Non-Clinical Performance Testing Conducted:

- Stem Fatigue Testing
- Wear Testing
- Durability Testing
- Modular Connection Fatigue Testing

Non-Clinical Performance Testing Conclusions:

Non-clinical testing demonstrated that the New Zimmer Total Elbow meets performance requirements as defined by Design Control activities and is substantially equivalent to the predicate device in terms of safety and efficacy.

In this case, clinical data and conclusions were not needed to demonstrate substantial equivalence.

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Attachment 3
2/27/13 email

(b)(4)

Zimmer Research Report

(b)(4)

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(b)(4),Test Report

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Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Attachment 7
2/27/13 email

zimmer

Traditional 510(k)
Executive Summary Premarket Notification

Device Name

Zimmer Nexel Total Elbow

Reason for the Submission

Zimmer is seeking clearance to market the Zimmer Nexel Total Elbow, which has not previously been marketed.

Device Description

Overview

The Zimmer Nexel Total Elbow is designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a constrained device assembly and consists of a *humeral component*, an *ulnar component*, a *humeral bearing-A*, 2 *ulnar bearings-B*, an *axle pin* and 2 *humeral screws*.

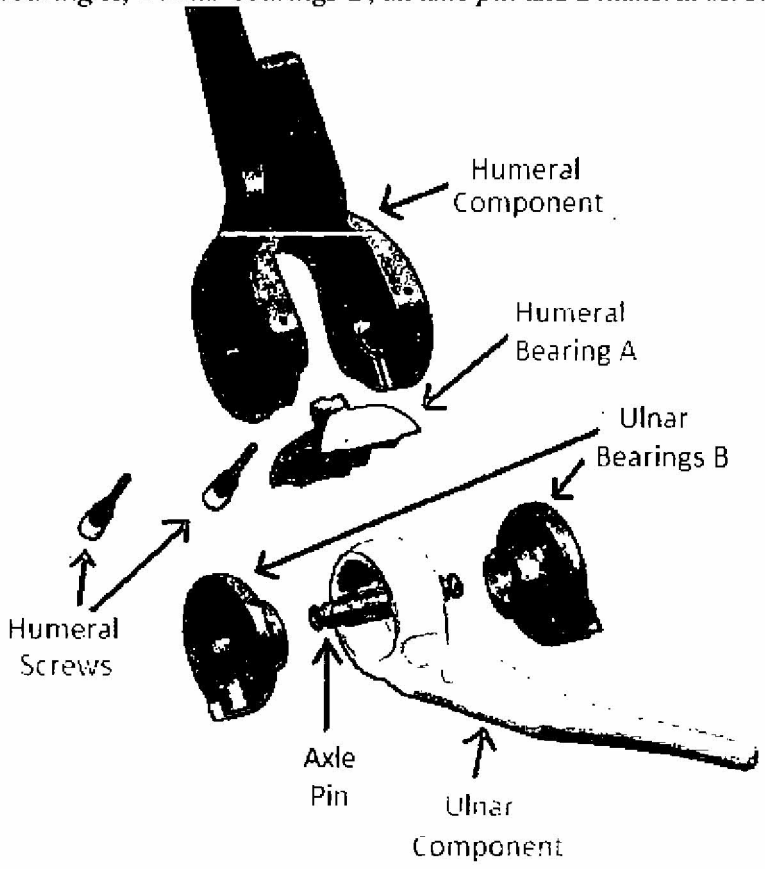

Image 10.1: The Zimmer Nexel Total Elbow, exploded view

A detailed description of the proposed device is presented in Section 11, Device Description.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

CAUTION: This device is intended for cemented use only.

Submission Overview

The table below provides a comparison between the proposed and predicate devices. Additional information is presented in Section 12, Substantial Equivalence Discussion.

		Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Humeral Component	Stem with Triangular Cross-Section	X	X
	Straight Stem	X	X
	Anterior Flange	X	X
	Titanium Alloy	X	X
	Titanium Beads on Distal Region		X
	Titanium Plasma Spray on Distal Region	X	
Ulnar Component	Stem with Quadrangular Cross-Section	X	X
	Curved Stem	X	X
	Nitrogen Enriched Surface Hardening of Ulnar Eye	X	
	Titanium Alloy	X	X
	Titanium Plasma Spray on Proximal Region	X	X
Linkage	2-Part, Hollow Snap-Pin		X
	Solid Axle Pin	X	
	Screws	X	
Constrained		X	X
Terminal Sterilization		X	X
Titanium-on-Polyethylene Articulation		X	X

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Performance Testing

The following performance testing was conducted on the Zimmer Nexel Total Elbow. A detailed summary and copy of each test report are included in Section 18, Performance Testing – Bench.

Stem Fatigue Testing

The fatigue strength of the Zimmer Nexel Total Elbow humeral component distal stem at (b)(4) load cycles is (b)(, which is (b)(stronger than that of the legally marketed Zimmer Coonrad/Morrey Total Elbow humeral component (b)(4 at a comparable point on the distal stem.

The fatigue strength of the Zimmer Nexel Total Elbow ulnar component stem in the mid-stem region at (b)(4) load cycles is at least (b)((the fatigue strength of the legally marketed Zimmer Coonrad/Morrey Total Elbow ulnar component at a comparable point on the stem).

The fatigue strength of the Zimmer Nexel Total Elbow ulnar component stem in the plasma spray (proximal stem) region at (b)(4) load cycles is at least (b)((the fatigue strength of the legally marketed Zimmer Coonrad/Morrey Total Elbow ulnar component at a comparable point on the stem).

These studies demonstrated that the Zimmer Nexel Total Elbow is at least as safe and effective as the predicate device (Zimmer Coonrad/Morrey Total Elbow) in terms of humeral and ulnar stem fatigue strength.

Wear Testing

The Zimmer Nexel Total Elbow mean gravimetric wear rate (b)(4) at (b)(4) load cycles) was (b) less than that of the predicate.

This study demonstrated that the Zimmer Nexel Total Elbow met or exceeded all acceptance criteria and is at least as safe and effective as the predicate device in terms of wear performance.

Durability Testing

The Zimmer Nexel Total Elbow device achieved (b)(4) run-outs at the equivalent of (b)(4) weight-in-hand (b)(4) peak JRF and (b)(4) varus-valgus moment), a load level (b) higher than the load level at which the predicate device ran out.

This study demonstrated that the Zimmer Nexel Total Elbow is at least as safe and effective as the predicate device in terms of durability.

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Modular Connection Fatigue Testing

The median fatigue strength of the non-articulating, mechanically locked, modular Zimmer Nexel Total Elbow implant components was no less than (b)(4

This study demonstrated that the Zimmer Nexel Total Elbow is safe and effective in terms of non-articulating, mechanically locked, modular connection fatigue.

Support Research

The following internal (Zimmer) research and testing informed and/or support the aforementioned testing and can be found in their entirety at the end of Section 18, Performance Testing – Bench.

- Zimmer Research Memo ZRM_WA_0179_09, *Analysis of Retrieved Coonrad/Morrey Elbow Total Arthroplasty Components*
- Zimmer Research Memo ZRM_WA_0193_09, *Development of the Coonrad/Morrey Elbow Durability Test*
- Zimmer Research Report ZRR_WA_1988_09, *Literature Review Summary of Elbow Joint Mechanics and Total Elbow Arthroplasty Outcomes*
- Zimmer Research Report ZRR_WA_2252_10, *Evaluation of the AS/BF Taper Adaptor Component Using Electrochemical Test Methods*
- Zimmer Technical Memo 1222.00, *Fatigue Strength of Plasma Sprayed Ti-6AL-4V Alloy Material*
- Zimmer Research Memo ZRM_WA_0292_11, *Summary of Clinical Complications of the Coonrad/Morrey Elbow System*
- Zimmer Research Report ZRR_WA_2338_11, *Vitamin E Highly Crosslinked Polyethylene Shelf Life Study*
- Zimmer Research Report ZRR_WI_2441_11, *Finite Element Analysis of the Coonrad-Morrey Total Elbow System*
- Zimmer Research Report ZRR_WA_2476_11, *Biomechanics Rationale for the Loading of Total Elbow Prosthesis During In Vitro Simulations*
- Zimmer Research Report ZRR_WA_2481_11, *Determination of the Functional Torque Range of the New Zimmer Total Elbow Humeral Screw and Hex Driver*
- Zimmer Technical Memo 1217.00, *Coonrad/Morrey Elbow Ulnar Stem Fatigue Testing*
- Zimmer Technical Memo 1218.00, *Coonrad/Morrey Humeral Stem Fatigue Testing*
- Memo to DHF File Z07-014, *Rationale for Determination of Torque Specification and Torque Range Requirement for the Mechanical Fastening Used in Zimmer New Total Elbow Prosthesis*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- Zimmer Research Report ZRR_WA_2646_12, *Pin-on-Flat Wear Comparison of the New Zimmer Total Elbow and the Coonrad-Morrey Articulation Couples*
- Zimmer Research Report ZRR_WA_2648_12, *Finite Element Analysis of Nexel Elbow Ulnar Implant Neck Region*
- Zimmer Research Report ZRR_WI_2441_11, *Finite Element Analysis of the Coonrad-Morrey Total Elbow System*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 5

2/27/13 email

zimmer

Traditional 510(k)
Premarket Notification

Device Description

Overview

The Zimmer Nexel Total Elbow is an implant designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a constrained device assembly and consists of the following components, which are described in more detail below:

- Humeral Component
- Ulnar Component
- Humeral Bearing-A
- 2 Ulnar Bearings-B
- Axle Pin
- 2 Humeral Screws

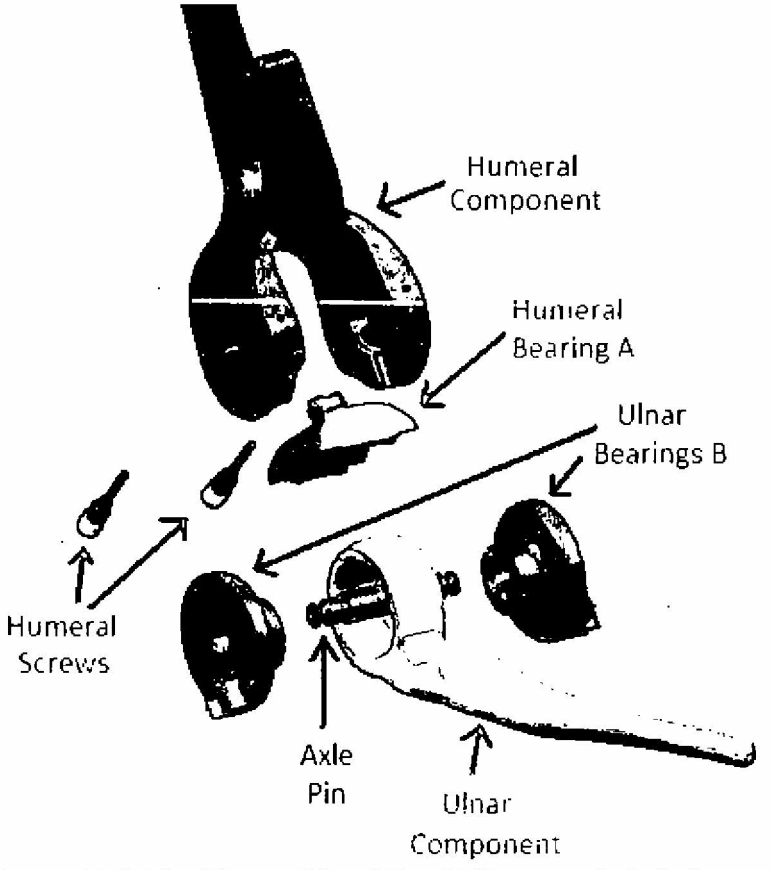

Image 11.1: The Zimmer Nexel Total Elbow, exploded view

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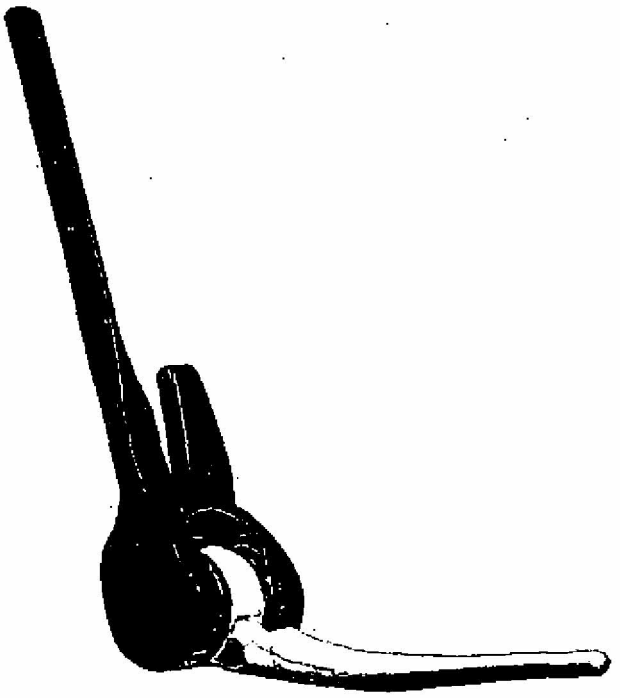

Image 11.2: The Zimmer Nexel Total Elbow, assembled

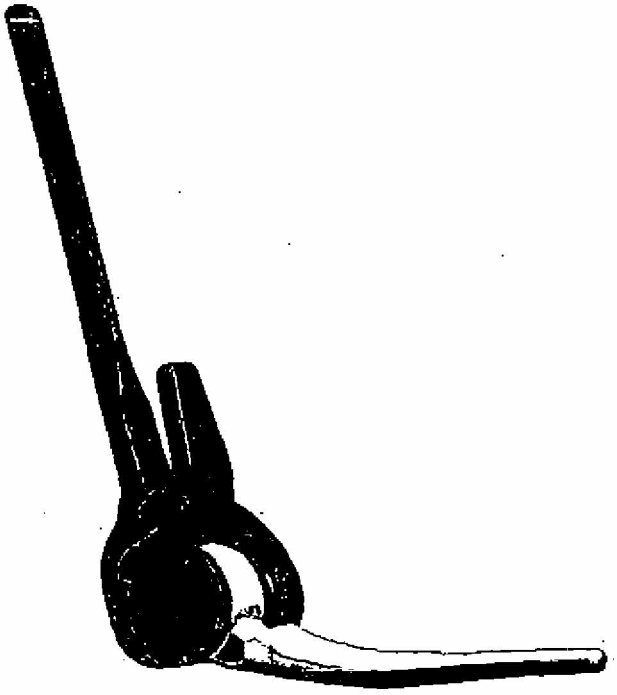

Image 11.3: The Zimmer Nexel Total Elbow, assembled with Humeral Component translucent

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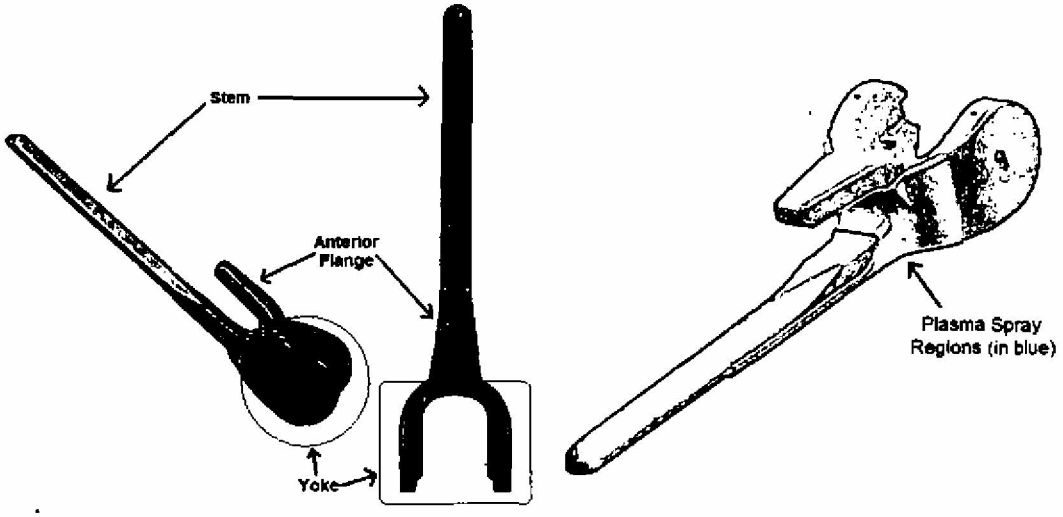
Humeral Component

The *humeral component* is made from wrought *Tivanium* alloy (Ti-6Al-4V) and has the following major design features: a *stem*, an *anterior flange*, a *yoke* and *plasma spray regions*.



Humeral Component, major design features

The *humeral stem* is intended to be implanted with bone cement into the patient's humeral medullary canal. It has a triangular cross-section, which is designed to prevent rotation of the *humeral component* within the patient's medullary canal; and, it is straight along its proximal-distal axis to conform to the straight shaft of the distal humeral medullary canal.

The *humeral anterior flange* is designed to accept a bone graft, which is wedged between the *anterior flange* and the exterior cortical bone of the humeral shaft. This *anterior flange* and bone graft combination are intended to improve both anti-rotational stability and posterior migration of the *humeral component*, thereby resisting stem loosening.

The *humeral yoke* has rounded corners (as opposed to angular) on its proximal surface in order to prevent stress risers (that are often associated with bone preparation cuts required for angled corners abutting bone). This rounded *yoke* design is intended to preserve the strength of (and avoid fracture of) the medial and lateral supracondylar columns. The *yoke* walls also house partially threaded holes with Spiralock® technology (tap manufactured by Stanley Black & Decker, Madison Heights, MI), which engage with the *humeral screws*.

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The *humeral component* has several regions covered in plasma spray, which is contained within the Plasma Sprayed Titanium-6Al-4V Alloy Coating Material Master File (FDA Ref: MAF-1909, Letter of Authorization can be found in Section 21). The *plasma spray regions* are designed to increase the coefficient of friction between the implant and the bone cement, thereby improving anti-rotational stability and aiding in resistance to movement of the implant with respect to the humerus.

In addition to the aforementioned major design features, the *humeral component* also includes the following features to accept the *axle-pin* and *bearings A and B*: v-grooves at the base of the keyways to accept the *axle-pin*, a hole to accept *humeral bearing-A* and two keyways to accept *ulnar bearings-B*.

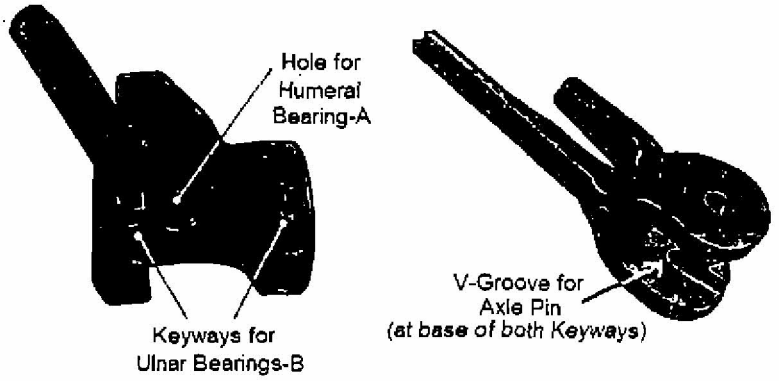

Image 11.5: Humeral Component, design features for mating to bearings and axle-pin

Ulnar Component

The *ulnar component* is made from wrought *Tivanium* alloy (Ti-6Al-4V) and has the following major design features: a *stem*, an *eye* and a *plasma spray region*.

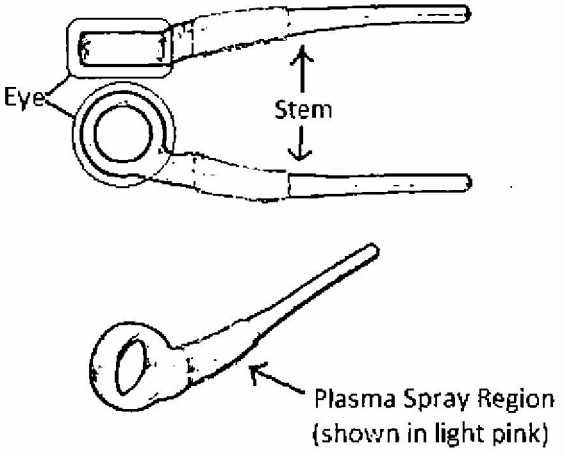

Image 11.6: Ulnar Component, major design features

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The *ulnar stem* is intended to be implanted with bone cement into the patient's ulnar medullary canal. It has a quadrangular cross-section, which is designed to prevent rotation of the *ulnar component* within the patient's medullary canal; and, it is curved along its proximal-distal axis to conform to the curved shaft of the proximal ulnar medullary canal.

The *ulnar eye* is both highly polished and nitrogen-enriched (as recommended in Section J, Titanium Articular Surface Coatings, of *Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented; Guidance for Industry and FDA*) to limit wear of the apposing *Bearings A and B* upon which it articulates.

The proximal portion of the *ulnar stem* is covered with plasma spray, which is contained within the Coatings Characterization of Orthopedic Titanium 6Al4V Coatings Material Master File (FDA Ref: MAF-652, Letter of Authorization can be found in Section 22). The *plasma spray region* is designed to increase the coefficient of friction between the implant and the bone cement, thereby improving anti-rotational stability and aiding in resistance to movement of the *ulnar stem* with respect to the ulna.

The *ulnar component* is side-specific, meaning that there is a left *ulnar component* and a right *ulnar component* available for every size offering.

Humeral Bearing-A

The *Humeral Bearing-A* is made from Vivacit-E™ (Vitamin E [α-tocopherol] stabilized, highly crosslinked ultra-high molecular weight polyethylene), which is contained within the Vitamin E Stabilized HXPE Material Master File authored by Zimmer (FDA Ref: MAF-1868). *Humeral bearing-A* is designed to articulate against the *ulnar component* throughout most of the humeroulnar joint range of motion, and has the following major design features: *concave articulation surface*, *anterior and posterior ridges*, a *peg*, four *peripheral bumps* and *medial and lateral rails*.

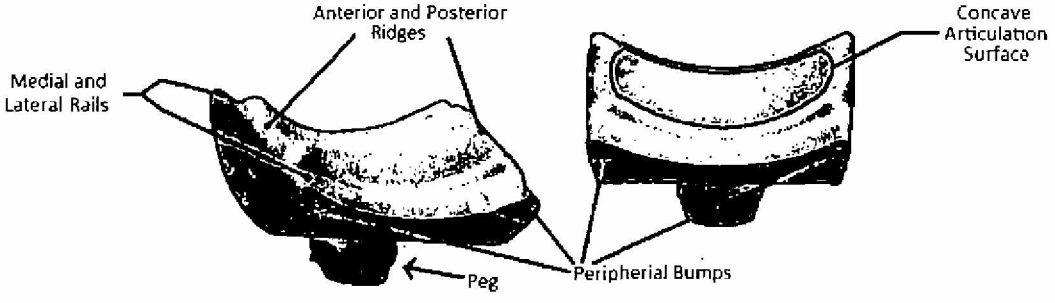

Image 11.7: Humeral Bearing-A, major design features

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The *humeral bearing-A concave articulation surface* is intended to (along with the articulation surface of the *ulnar bearings-B*) allow for load sharing from the ulnar component onto *humeral bearing-A* throughout most of the range of motion of the humeroulnar joint. The *posterior ridge* specifically supports high-flexion motions (see Image 11.8, below). The *humeral bearing-A anterior ridge* is symmetrical to the *posterior ridge* in order to remove the human factors issue of having to discern anterior from posterior when assembling *humeral bearing-A* to the *humeral component*: *humeral bearing-A* cannot be put in backwards, because it is symmetrical.

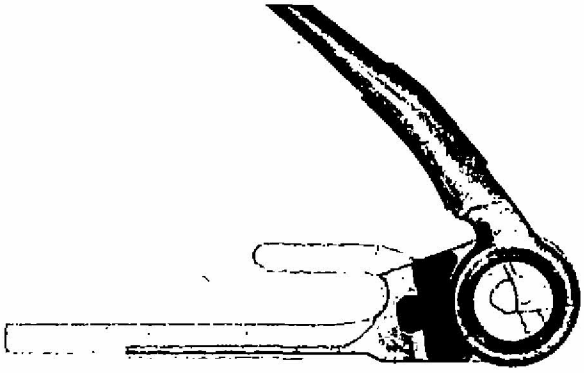

Image 11.8: Posterior Ridge of Humeral Bearing-A supporting high flexion of the ulnar component with respect to the humeral component

The *humeral bearing-A peg* is designed to mate to the hole at the proximal base of the *humeral yoke* with a press (not a snap) fit, which is intended to limit motion between *humeral bearing-A* and the *humeral yoke*.

The *humeral bearing-A* (four) *peripheral bumps* are designed to mate against the interior walls of the *humeral yoke* with a press-fit, which is intended to limit motion (and therefore backside wear) of the *humeral bearing-A* relative to the *humeral yoke*.

The humeral bearing-A *medial and lateral rails* are designed to allow clearance for (as opposed to a direct mate with) *ulnar bearings-B*, which directly mate to the *humeral yoke* and to the *axle pin*.

Note: The *humeral bearing-A* may also be referred to as "humeral bearing" and "bearing A" throughout this submission.

Ulnar Bearings-B

The *ulnar bearings-B* (two per implant assembly) are made from Vivacit-E™ (Vitamin E [α-tocopherol] stabilized, highly crosslinked ultra-high molecular weight polyethylene), which is contained within the Vitamin E Stabilized HXPE Material

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Master File authored by Zimmer (FDA Ref: MAF-1868). *Ulnar bearings-B* are designed to articulate against the *ulnar component* throughout the entire humeroulnar joint range of motion, and have the following major design features: *articulation surface, anti-rotation key, through-hole* and *compressible semi-circle*.

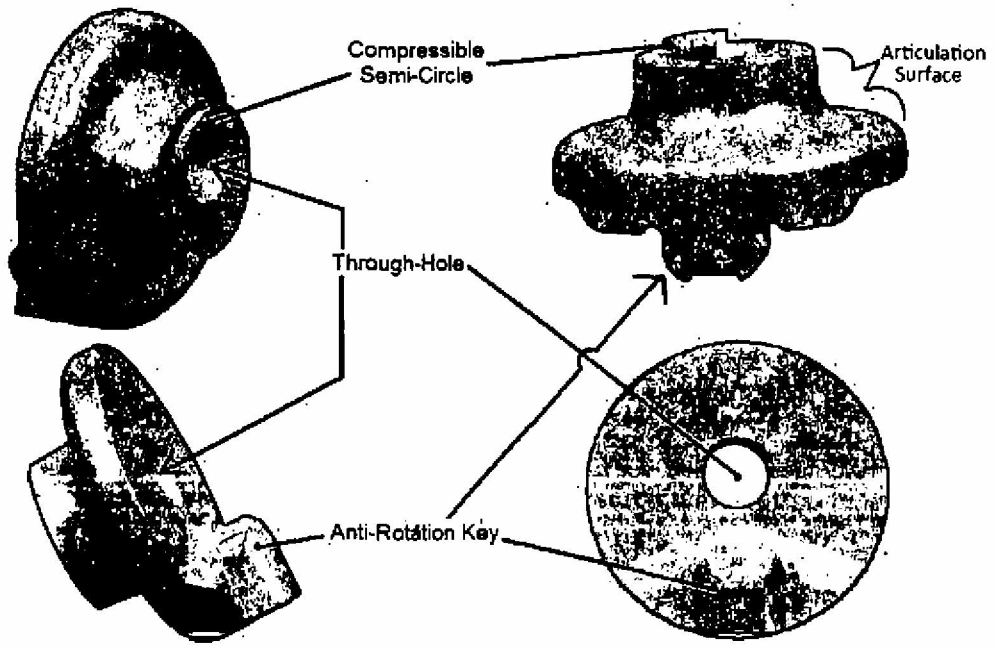

Image 11.9: Ulnar Bearings-B, major design features

The *ulnar bearings-B articulation surface* is intended to (along with the articulation surface of the *ulnar bearing-A*) allow for load sharing from the *ulnar component* onto *humeral bearing-B* throughout the range of motion of the humeroulnar joint.

The *ulnar bearings-B anti-rotation keys* mate into the *humeral yoke keyways* with a press-fit to limit translational and rotational motion of *ulnar bearings-B* with respect to the *humeral component*.

The *compressible semi-circle* of one *ulnar bearing-B* is designed to align with the *compressible semi-circle* of the second *ulnar bearing-B* such that a nearly full circle is created. This design feature is intended to ensure proper alignment of *ulnar bearings-B* with respect to each other (during assembly of *ulnar bearings-B* to the *axle pin* using the *ulnar bearing assembly tool*) and, after proper assembly to the *axle pin*, to the *humeral yoke keyways*. Due to the fact that the *compressible semi-circle* is more easily deformed than the broad, apposing faces of *ulnar bearings-B*, it creates a press-fit between the *ulnar bearings-B* and between each *ulnar bearing-B* and the apposing interior walls of the *humeral yoke*. This press-fit is intended to limit mediolateral motion of the *ulnar bearings-B* along the *axle-pin*, thereby limiting backside wear of the *ulnar bearings-B*.

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The *ulnar bearings-B through-hole* mates around the *axle pin* with a press-fit intended to limit motion of *ulnar bearings-B* with respect to the *axle pin*, and thus limit backside wear of *ulnar bearings-B*. The position of the *through-hole* is eccentric (with respect to the outer diameter of *ulnar bearings-B*) in order to place the largest cross-section of Vivacit-E™ material in opposition to the highest loads (Joint Reaction Forces, JRFs) induced throughout the flexion-extension cycle of the humeroulnar joint (see image 11.10, below).

Note: The *ulnar bearings-B* do NOT mate to or in any way interface with the *humeral screws*.

Note: The *ulnar bearings-B* may also be referred to as "ulnar bearing(s)" and "bearing(s) B" throughout this submission.

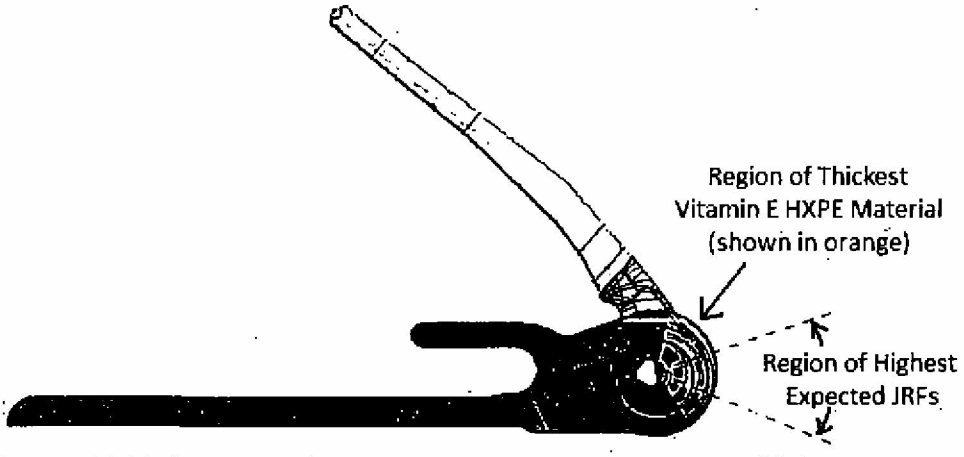

Image 11.10: Thickest Vitamin E HXPE placement to oppose highest JRFs

Axle Pin

The *axle pin* is made from *Zimaloy* (Cobalt-Chromium-Molybdenum Alloy), is designed to remain in a fixed position (not translate nor rotate) throughout the entire humeroulnar joint range of motion, and has the following major design feature: *v-groove*.

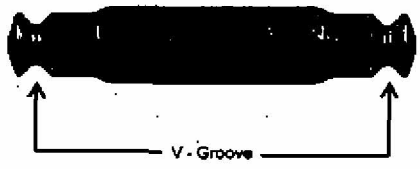

Image 11.11: Axle Pin, major design feature

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The *v-groove* is designed to mate with the taper of the *humeral screws* that, upon screw thread engagement in the *humeral yoke*, rigidly compresses the *axle pin* against the *humeral yoke*.

Additionally, the *axle pin* is designed to rigidly mate with *ulnar bearings-B*, the *humeral screws* and the *humeral yoke*, creating a rigid assembly along which joint reaction forces are intended to be shared.

Note: The *axle-pin* may also be referred to as "axle" throughout this submission.

Humeral Screws

The *humeral screws* (two per implant assembly) are made from *Zimaloy* (Cobalt-Chromium-Molybdenum Alloy), are designed to remain in a fixed position throughout the entire humeroulnar joint range of motion, and have the following major design features: *headless*, *threads*, *pilot* and *taper*.

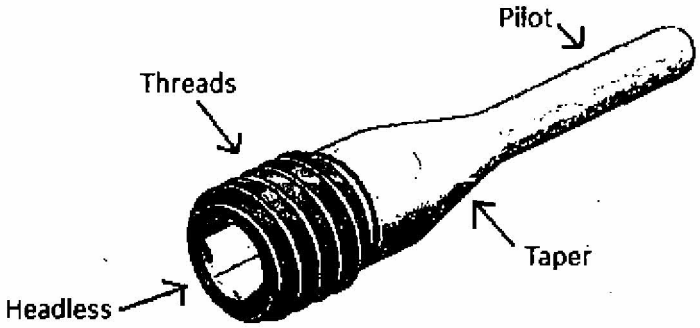

Image 11.12: Humeral Screws, major design feature

The *humeral screw threads* engage with threads of the *humeral yoke* while the *humeral screw pilot* engages a hole in the wall of the *humeral yoke* and the *humeral screw taper* engages with the *axle pin v-groove*, compressing the ends of the *axle pin* against the *v-groove* at the base of the *humeral yoke keyway*.

The *humeral screws* are *headless*, a feature that allows the *humeral screws* to countersink into the *humeral yoke*, which is intended to ensure the constant application of a clamp-load to the *axle-pin* and to avoid soft tissue impingement or irritation associated with a protruding screw head.

Note: While the *humeral screws* are designed to apply a consistent clamp-load to the *axle pin*, they are *not* directly loaded by any compressive joint reaction force (JRF) during the flexion-extension cycle (this design feature is intended to avoid screw back-out by not allowing any complete transverse load-reversal across the *humeral screw threads*). Instead, compressive JRFs are transmitted from the *ulnar implant*

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component to the *ulnar bearings-B* to the *axle pin* to the *v-grooves* at the base of the *humeral yoke keyways* and finally throughout the *humeral component*. See Zimmer Research Report ZRR_WA_2598_12, *New Zimmer Total Elbow Prosthesis Modular Connection Fatigue Testing* for a more detailed explanation.

System Compatibility

No Zimmer Nexel Total Elbow component is compatible with any device outside the Zimmer Nexel Total Elbow system.

Size Interchangeability

All Zimmer Nexel Total Elbow *humeral component* sizes are designed to mate with all Zimmer Nexel Total Elbow *ulnar component* sizes. The *axle pin* size 4, *humeral bearing-A* size 4, and *ulnar bearings-B* size 4 are designed to mate with all size 4 *humeral components*. The *axle pin* size 5/6, *humeral bearing-A* size 5/6, and *ulnar bearings-B* size 5/6 are designed to mate with all size 5 and size 6 *humeral components*. The *humeral screws* are designed to mate with all Zimmer Nexel Total Elbow *humeral components* and *axle pin* sizes.

Engineering Drawings

Representative engineering drawings for the proposed device are included at the end of this section.

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Catalog Numbers

All catalog numbers for the Zimmer Nexel Total Elbow are listed below.

Catalog Number	Description
00-8400-014-07	Zimmer Nexel Total Elbow - Ulnar Stem, Size 4, 75 mm, Left
00-8400-014-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 4, 115 mm, Left
00-8400-024-07	Zimmer Nexel Total Elbow - Ulnar Stem, Size 4, 75 mm, Right
00-8400-024-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 4, 115 mm, Right
00-8400-015-07	Zimmer Nexel Total Elbow - Ulnar Stem, Size 5, 75 mm, Left
00-8400-015-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 5, 115 mm, Left
00-8400-025-07	Zimmer Nexel Total Elbow - Ulnar Stem, Size 5, 75 mm, Right
00-8400-025-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 5, 115 mm, Right
00-8400-016-09	Zimmer Nexel Total Elbow - Ulnar Stem, Size 6, 90 mm, Left
00-8400-016-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 6, 115 mm, Left
00-8400-026-09	Zimmer Nexel Total Elbow - Ulnar Stem, Size 6, 90 mm, Right
00-8400-026-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 6, 115 mm, Right
00-8400-044-10	Zimmer Nexel Total Elbow - Humeral Stem, Size 4, 100 mm
00-8400-044-15	Zimmer Nexel Total Elbow - Humeral Stem, Size 4, 150 mm
00-8400-045-10	Zimmer Nexel Total Elbow - Humeral Stem, Size 5, 100 mm
00-8400-045-15	Zimmer Nexel Total Elbow - Humeral Stem, Size 5, 150 mm
00-8400-055-15	Zimmer Nexel Total Elbow - Humeral Stem, Long Flange, Size 5, 150 mm
00-8400-055-20	Zimmer Nexel Total Elbow - Humeral Stem, Long Flange, Size 5, 200 mm
00-8400-046-10	Zimmer Nexel Total Elbow - Humeral Stem, Size 6, 100 mm
00-8400-046-15	Zimmer Nexel Total Elbow - Humeral Stem, Size 6, 150 mm
00-8400-056-15	Zimmer Nexel Total Elbow - Humeral Stem, Long Flange, Size 6, 150 mm
00-8400-056-20	Zimmer Nexel Total Elbow - Humeral Stem, Long Flange, Size 6, 200 mm
Kit # 00-8400-094-00 00-8400-194-01 00-8400-194-02 00-8400-194-04	*Zimmer Nexel Total Elbow - Articulation Kit, Size 4* Kit Contents: 1 Humeral Bearing-A Size 4 2 Ulnar Bearings- B Size 4 1 Axle Pin Size 4
Kit # 00-8400-095-00 00-8400-195-01 00-8400-195-02 00-8400-195-04	*Zimmer Nexel Total Elbow - Articulation Kit, Size 5/6* Kit Contents: 1 Humeral Bearing-A Size 5/6 2 Ulnar Bearings- B Size 5/6 1 Axle Pin Size 5/6
Kit # 00-8400-090-00 00-8400-190-00	*Zimmer Nexel Total Elbow - Humeral Screw Kit* Kit Contents: 2 Humeral Screws

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Materials

The *humeral and ulnar components* are made of wrought *Tivanium* alloy (Ti-6Al-4V) and are titanium plasma sprayed (on regions specified in the engineering drawings at the end of this section). The *bearings A and B* are made of *Vitamin E HXPE* (Vitamin E Highly Crosslinked Polyethylene). The *axle pin* and *humeral screws* are made of *Zimaloy* (Cobalt-Chromium-Molybdenum Alloy).

The following tests contained within the Material Master File for Vitamin E Stabilized Highly Crosslinked Polyethylene (Master File MAF-1868) are applicable to usage in elbow devices and support substantial equivalence of the Vitamin E Stabilized HXPE material when used in elbow devices:

Report Number	Report Name	Master File Location
ZRR_WA_2401_11 Rev. 2	TESTING OF VITAMIN E HIGHLY CROSSLINKED POLYETHYLENE PROPERTIES PER ASTM F2759-09	Amendment 02, Exhibit B
N102082	NAMSA - TOXICOLOGICAL RISK ASSESSMENT	Volume 1, Page 54
T0118_913/S	13 WEEK SYSTEMIC TOXICITY STUDY IN RATS FOLLOWING SUBCUTANEOUS IMPLANTATION	Volume 1, Page 86
V0014_130	CYTOTOXICITY STUDY USING THE ISO ELUTION METHOD	Volume 1, Page 76
V0023_211	BACTERIAL REVERSE MUTATION STUDY - EXTRACTS	Volume 1, Page 108
V0573_000/S	GENOTOXICITY: MOUSE LYMPHOMA ASSAY	Volume 1, Page 125
T0566_500, T0566_501	MOUSE PERIPHERIAL BLOOD MICRONUCLEUS STUDY	Volume 1, Pae 147
T1251_800	ISO INTRACUTANEOUS STUDY IN RABBITS	Volume 1, Page 179
T1261_300	ISO GUINEA PIG MAXIMIZATION SENSITIZATION TEST	Volume 1, Page 189
T1250_812	ISO MUSCLE IMPLANTATION STUDY IN RABBITS - 12 WEEKS	Volume 1, Page 205
T1250_802	ISO MUSCLE IMPLANTATION STUDY IN RABBITS - 2 WEEKS	Volume 1, Page 217
ZRR_WA_2338_11	VITAMIN E HIGHLY CROSSLINKED POLYETHYLENE SHELF LIFE STUDY	Volume 1, Page 230
T02625-500	ISO SYSTEMIC TOXICITY STUDY IN MICE	Volume 1, Page 245
T0118_926	26 WEEK SYSTEMIC TOXICITY STUDY IN RATS FOLLOWING SUBCUTANEOUS IMPLANTATION	Volume 1, Page 256
ZRR_WA_2424_11	EVALUATION OF VITAMIN E DOPED AND CROSSLINKED UHMWPE WEAR DEBRIS IN THE RABBIT KNEE FOLLOWING PERCUTANEOUS INJECTION	Amendment 01, Page 9

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Report Number	Report Name	Master File Location
10T_60283_02	BIOLOGICAL RESPONSE TO WEAR DEBRIS Note: The particulate study was done to detect local and systemic response to vitamin E grafted UHMWPE. A rabbit model which is widely accepted was used. The particulates were produced from production materials and have size distribution that is representative of those that have been isolated from tissues harvested during hip or knee revision surgeries. The particles were injected directly into the knee capsule of the animals. This study was not focused on any particular implant or device. The emphasis was on inflammatory response to the particulates. The study covered all devices that generate particulates.	Volume 2, Page 243
ZRR_WA_2409_11	VIATMIN E STABILIZED HIGHLY CROSSLINKED POLYETHYLENE EXTENDED AGING STUDY	Volume 2, Page 394
ZRR_WA_2373_11	ENVIRONMENTAL STRESS CRACKING OF VITAMIN E, LONGEVITY, CONVENTIONAL UHMWPE	Volume 2, Page 422
ZRR_WA_2403_11	VITAMIN E STABILIZED HIGHLY CROSSLINKED POLYETHYLENE- EXTRACTABILITY STUDY	Volume 2, Page 441
ZRR_WA_2412_11	VITAMIN E STABILIZED HIGHLY CROSSLINKED POLYETHYLENE- PRESSURE INDUCED LEACHING	Volume 2, Page 492
ZRR_WA_2382_11	VITAMIN E STABILIZED HIGHLY CROSSLINKED POLYETHYLENE- TRANSFORMATION PRODUCTS EVALUATION BY HPLC AND GC	Volume 2, Page 507
ZRM_WA_0293_11	LAMELLAE THICKNESS	Volume 2, Page 566
ZRM_WA_0277_11	MOLECULAR WEIGHT	Volume 2, Page 578
CPG REPORT_ 11622_1	GC/MS ANALYSIS OF UHMWPE	Amendment 02, Exhibit A

Surface Characteristics

The *eye* of the *ulnar component* is treated with a nitrogen ion implantation (also known as nitriding) process (to increase *Tivanium* alloy surface hardness) on the region specified in the engineering drawings at the end of this section.

The articulating surfaces of the *ulnar component* are polished to an R_a value of (b)(4) or less and the articulating surfaces of the *bearings A and B* are machined to an R_a value of (b)(4) or less to provide for smooth articulating surfaces.

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Mechanism of Action

The Zimmer Nexel Total Elbow implant assembly is a constrained prosthesis designed to allow anatomic reconstruction of the humeroulnar joint with the natural change in humeroulnar joint center of rotation throughout the flexion/extension arc based on research presented in the Zimmer Research Report ZRR_WA_2476_11, *Biomechanics Rationale for the Loading of Total Elbow Prosthesis During In Vitro Simulations*. See table below for range of motion details.

	Feature		Proposed Device: The Zimmer Nexel Total Elbow
Range of Motion (defined in terms of Ulnar Component movement with respect to Humeral Component)	Varus/Valgus Angular Laxity		Neutral to Maximum Varus: (b) Neutral to Maximum Valgus: (4) Total Included Angle: (b)
	Internal/External Rotational Laxity		Neutral to Maximum Internal Rotation: (b) Neutral to Maximum External Rotation: (4) Total Included Angle: (b)
	Pistoning	Proximal/Distal Translational Laxity	Neutral to Maximum Proximal: (b)(4) Neutral to Maximum Distal: Total Proximal/Distal Laxity:
		Anterior/Posterior Translation Laxity	Neutral to Maximum Anterior: Neutral to Maximum Posterior: Total Anterior/Posterior Laxity:
	Medial/Lateral Translation Laxity		Neutral to Maximum Medial: Neutral to Maximum Lateral: Total Medial/Lateral Laxity:
	Flexion/Extension Range (defined in terms of degrees flexion)		All Humeral and Ulnar size combinations: (b)(4)

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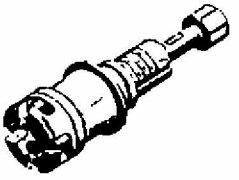
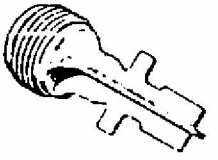
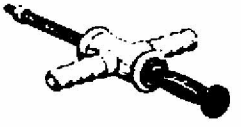
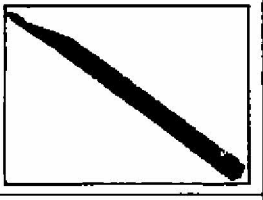
Surgical Instrumentation Unique to the Device

Following are the instruments unique to the Zimmer Nexel Total Elbow. These are Class II accessories to the device. Applicable material standards are listed in a table at the end of this section.

The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
(Table Continued on Next Page)

Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-002-00	T-Handle	17-4 SS 303 SS 420 SS 316 SS	yes		Quick-connect handle for use with humeral and ulnar rasps.
00-8401-008-00	Reciprocating Saw Adapter	303 SS 420 SS 316 SS	yes		Adapter to connect humeral and ulnar rasps to a compatible large bone reciprocating saw via the single use connector.
00-8401-008-01	Single Use Connector	455 SS	yes, skin only		Connects the reciprocating saw adaptor to a compatible large-bone reciprocating saw.
00-8401-009-00	Slide Hammer	17-4 SS 304 SS 17-4 SS	yes		Mates with humeral and ulnar stem extractors to deliver impact blows when extractor component is attached to the implant.
00-8401-018-00	Ulnar Bearing Tamp	17-4 SS	yes		To compress the articulating assembly (ulnar bearings and axle pin) into the humeral implant. (An alternate instrument to the articulation inserter.)
00-8401-012-04	Trephine Stabilizer, Size 4	17-4 SS	yes		Guides the finishing cut of the trephine through the anterior aspect of the humerus.
00-8401-012-05	Trephine Stabilizer, Size 5	17-4 SS	yes		

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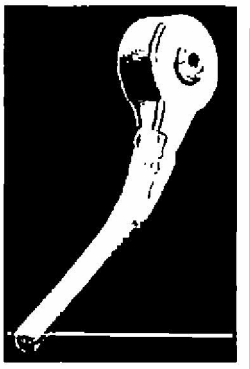
The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
(Table Continued from Previous Page, Continued on Next Page)

Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-014-07	Ulnar Provisional, Size 4, 75 mm, Left	17-4 SS	yes		To assess the bone preparation of the ulnar medullary canal, and to allow an intraoperative range of motion.
00-8401-014-11	Ulnar Provisional, Size 4, 115 mm, Left	17-4 SS	yes		
00-8401-015-07	Ulnar Provisional, Size 5, 75 mm, Left	17-4 SS	yes		
00-8401-015-11	Ulnar Provisional, Size 5, 115 mm, Left	17-4 SS	yes		
00-8401-016-09	Ulnar Provisional, Size 6, 90 mm, Left	17-4 SS	yes		
00-8401-016-11	Ulnar Provisional, Size 6, 115 mm, Left	17-4 SS	yes		
00-8401-024-07	Ulnar Provisional, Size 4, 75 mm, Right	17-4 SS	yes		
00-8401-024-11	Ulnar Provisional, Size 4, 115 mm, Right	17-4 SS	yes		
00-8401-025-07	Ulnar Provisional, Size 5, 75 mm, Right	17-4 SS	yes		
00-8401-025-11	Ulnar Provisional, Size 5, 115 mm, Right	17-4 SS	yes		
00-8401-026-09	Ulnar Provisional, Size 6, 90 mm, Right	17-4 SS	yes		
00-8401-026-11	Ulnar Provisional, Size 6, 115 mm, Right	17-4 SS	yes		
00-8401-019-00	Articulation Inserter	17-4 SS	yes		To compress the articulating assembly (ulnar bearings and axle pin) and ulnar implant into the humeral implant. Also, to compress the humeral bearing into the humeral implant. (This is an alternate instrument to the ulnar bearing tamp and the humeral bearing driver.)
00-8401-028-00	Ulnar Stem Inserter	Radel	yes		To transmit force to insert the ulnar implant without damaging the articular surface.

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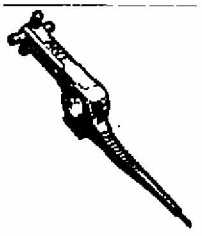
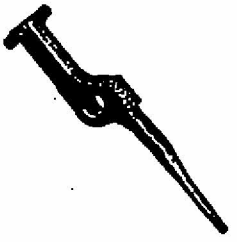
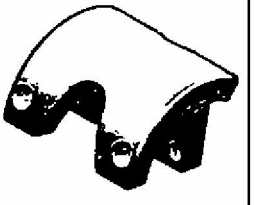
The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
(Table Continued from Previous Page. Continued on Next Page)

Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-029-00	Implant Extractor Hook	17-4 SS	yes		To transmit force from the slide hammer to an implanted ulnar implant or humeral implant to facilitate their removal. The extractor hook is attached to the slide hammer by a threaded connection.
00-8401-033-01	Ulnar Rasp, Pilot, Left	17-4 SS	yes		Removes bone from the ulnar medullary canal and olecranon and shapes the medullary canal to create a precise geometry for a size-matched ulnar implant. Can be mated to the reciprocating saw adaptor or to the T-handle.
00-8401-033-02	Ulnar Rasp, Pilot, Right	17-4 SS	yes		
00-8401-034-01	Ulnar Rasp, Size 4/5, Left	17-4 SS	yes		
00-8401-034-02	Ulnar Rasp, Size 4/5, Right	17-4 SS	yes		
00-8401-036-01	Ulnar Rasp, Size 6, Left	17-4 SS	yes		
00-8401-036-02	Ulnar Rasp, Size 6, Right	17-4 SS	yes		
00-8401-039-00	Ulnar Clearance Template	17-4 SS	yes		To check for adequate bone removal on the medial and lateral sides of the ulna for clearance for the articulation insertion instruments.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
(Table Continued from Previous Page. Continued on Next Page)

Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-044-10	Humeral Provisional, Size 4, 100 mm	17-4 SS	yes		Dimensionally represents the humeral implant to help assess the preparation of the humeral medullary canal, and to intraoperatively check range of motion.
00-8401-044-15	Humeral Provisional, Size 4, 150 mm	17-4 SS	yes		
00-8401-045-10	Humeral Provisional, Size 5, 100 mm	17-4 SS	yes		
00-8401-045-15	Humeral Provisional, Size 5, 150 mm	17-4 SS	yes		
00-8401-046-10	Humeral Provisional, Size 6, 100 mm	17-4 SS	yes		
00-8401-046-15	Humeral Provisional, Size 6, 150 mm	17-4 SS	yes		
00-8401-055-15	Humeral Provisional, Long Flange, Size 5, 150mm	17-4 SS	yes		
00-8401-055-20	Humeral Provisional, Long Flange, Size 5, 200mm	17-4 SS	yes		
00-8401-056-15	Humeral Provisional, Long Flange, Size 6, 150mm	17-4 SS	yes		
00-8401-056-20	Humeral Provisional, Long Flange, Size 6, 200mm	17-4 SS	yes		
00-8401-058-04	Humeral Stem Inserter, Size 4	17-4 SS	yes		To insert the humeral implant into the humeral canal without damaging the humeral bearing.
00-8401-058-05	Humeral Stem Inserter, Size 5/6	17-4 SS	yes		
00-8401-059-04	Humeral Extractor Plate, Size 4	17-4 SS	yes		To transmit force from slide hammer to humeral implant in order to facilitate removal. Extractor plate is attached to humeral implant by the humeral extractor screws.
00-8401-059-05	Humeral Extractor Plate, Size 5/6	17-4 SS	yes		

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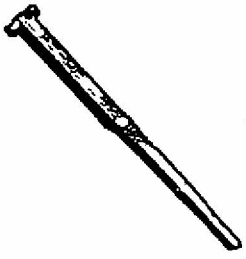
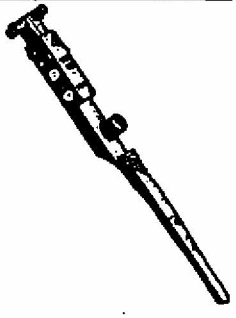
The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
(Table Continued from Previous Page. Continued on Next Page)

Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-060-00	Humeral Awl Reamer	17-4 SS	yes		To open the humeral medullary canal. Also, provides a means of ensuring the trochlear resection is adequate to *accept subsequent humeral* rasps.
00-8401-061-00	I/E Alignment Rod	17-4 SS	yes		To assess and adjust, if necessary, the internal/external rotation of the humeral and ulnar rasps.
00-8401-064-00	Humeral Rasp, Pilot	17-4 SS	yes		Removes bone from the humeral medullary canal to create a precise geometry for a size-matched humeral implant. Humeral rasps also used to orient and securely support the humeral cut guide, and to guide the trephine cut.
00-8401-064-10	Humeral Rasp, Size 4, 100 mm	17-4 SS	yes		
00-8401-064-15	Humeral Rasp, Size 4, 150 mm	17-4 SS	yes		
00-8401-065-10	Humeral Rasp, Size 5, 100 mm	17-4 SS	yes		
00-8401-065-15	Humeral Rasp, Size 5, 150 mm	17-4 SS	yes		
00-8401-066-10	Humeral Rasp, Size 6, 100 mm	17-4 SS	yes		
00-8401-066-15	Humeral Rasp, Size 6, 150 mm	17-4 SS	yes		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
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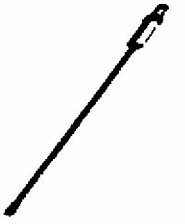
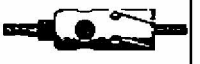
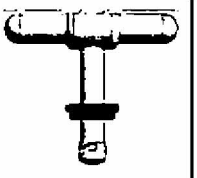
Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-070-45	Flexible Solid Reamer, 4.5 mm	13-8 SS	yes		To remove bone from the ulnar medullary canal. Connects to a surgical drill or reamer driver.
00-8401-070-05	Flexible Solid Reamer, 5 mm	13-8 SS	yes		
00-8401-072-01	Flexible Cannulated Reamer, 5.5 mm	13-8 SS	yes		Mates over the guide wire. Used to remove bone from the ulnar and humeral medullary canals. Connects to a surgical drill or reamer driver.
00-8401-072-02	Flexible Cannulated Reamer, 6 mm	13-8 SS	yes		
00-8401-072-03	Flexible Cannulated Reamer, 6.5 mm	13-8 SS	yes		
00-8401-072-04	Flexible Cannulated Reamer, 7 mm	13-8 SS	yes		
00-8401-072-05	Flexible Cannulated Reamer, 8 mm	13-8 SS	yes		
00-8401-072-06	Flexible Cannulated Reamer, 9 mm	13-8 SS	yes		
00-8401-072-07	Flexible Cannulated Reamer, 10 mm	13-8 SS	yes		
00-8401-072-08	Flexible Cannulated Reamer, 11 mm	13-8 SS	yes		
00-8401-072-09	Flexible Cannulated Reamer, 12 mm	13-8 SS	yes		
00-8401-074-00	Trephine, Size 4	17-4 SS 13-8 SS	yes		Removes bone from the distal humerus to accept a given size-matched humeral implant. Connects to a surgical drill.
00-8401-075-00	Trephine, Size 5/6	17-4 SS 13-8 SS	yes		
00-8401-078-00	Humeral Bearing Driver	17-4 SS	yes		To deliver a compressive force sufficient to fully seat the humeral bearing into the humeral implant when used with the humeral bearing driver pin. Also used to install a humeral bearing component into the humeral implant during a revision surgery. (This is an alternate instrument to the articulation inserter.)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
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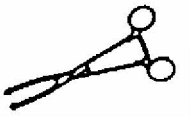
Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-079-00	Humeral Bearing Driver Pin	440A SS	yes		Subcomponent of the humeral bearing driver. Can also be used to aid in internal/external alignment of the ulnar provisionals.
00-8401-081-00	Ulnar Bearing Assembly Tool	17-4 SS 455 SS 316 SS	yes		To assemble the axle pin to ulnar bearings-B; and, to assemble the ulnar bearings-B onto the axle pin through the proximal head of the ulnar Implant. Performed by compressing the handle of the tool manually. To be used in situ.
00-8401-082-00	Humeral Bearing Placement Tool	420 SS 304 SS	yes		To place humeral bearing-A into the base of the humeral implant yoke.
00-8401-084-00	Humeral Screw Holder, Size 4	17-4 SS	yes		To securely hold the humeral screws and align the screws to a size-matched humeral implant.
00-8401-085-00	Humeral Screw Holder, Size 5/6	17-4 SS	yes		
00-8401-088-00	Humeral Screw Installation Driver Bit	440C SS LDPE	yes		Connects to the humeral screw installation driver to install the humeral screws into the humeral implant, and prevents the user from over-torquing the humeral screws. An alternative to the torque-limiting humeral screw driver, below. NOTE: *Cannot* mate with the humeral screw removal driver.
00-8401-089-00	Humeral Screw Removal Driver	455 SS 303 SS Silicone	yes		To remove the humeral screws from the humeral implant only when mated with the humeral screw removal driver bit. NOTE: Will *not* allow installation torque to be applied.
00-8401-091-00	Humeral Bearing Extractor	17-4 SS	yes		To remove the humeral bearing from the humeral implant.
00-8401-092-00	Articulation Extractor	17-4 SS	yes		To remove the articulation assembly (ulnar bearings and axle pin) and ulnar implant from the humeral implant.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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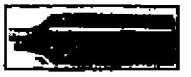
The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
(Table Continued from Previous Page. End of Table)

Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-093-00	Humeral Extractor Screw	455 SS	yes		Attaches the humeral extractor plate to the humeral implant to facilitate humeral component extraction.
00-8401-097-00	Humeral Screw Removal Driver Bit	440C SS 316 SS	yes		Used with the humeral screw removal driver. NOTE: *Cannot* mate with the humeral screw installation driver.
00-8401-004-00	Humeral Cut Guide, Size 4	17-4 SS	yes		Connects to humeral rasps. Used to facilitate the creation of parallel cuts equidistant from the longitudinal axis of the rasp when used with a surgical blade.
00-8401-005-00	Humeral Cut Guide, Size 5/6	17-4 SS	yes		
00-8401-080-00	Torque-Limiting Humeral Screw Driver	440C SST Ultem	yes		To install and remove the humeral screws into and from the humeral implant. Prevents the user from over-torquing the humeral screws upon insertion. This instrument is intended to be used for a single surgery only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Surgical Instrumentation Not Unique to the Device

Following are the instruments not unique to the Zimmer Nexel Total Elbow. These are Class I instruments currently able to be used with other surgical devices cleared for market in the United States.

The Zimmer Nexel Total Elbow – Class I Instruments	
Catalog Number	Description
00-4812-035-00	Small Hex Screwdriver
47-2255-008-00	Sterile Ball Tip Guide Wire 2.4 x 70
31-8106-168-00	Ulnar Awl Reamer
00-4811-035-01	Humeral Screw Installation Driver
00-5049-053-00	Quick Use Curette

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Instrument Material Standards

The Zimmer Nexel Total Elbow: Instrument Material Standards	
Material	**Applicable Standards per Zimmer Engineering Specifications**
6061-T6 Aluminum	ASTM B209, ASTM B211, ASTM B221
13-8 SS	ASTM A484, ASTM A555, ASTM A564
17-4 SS	ASTM A484, ASTM F899
18-8 SS	ASTM A484, ASTM A555, ASTM A580
303 SS	ASTM F899
304 SS	ASTM A276, ASTM A484
316 SS	ASTM F899
316L SS	ASTM F138, ASTM F139, ASTM 1350, ISO 5832-1
420 SS	ASTM F899
440A SS	ASTM F899, ASTM A555
440C SS	ASTM F899
455 SS	ASTM F899, ISO 7153-1
Phenolic	No Standard Applicable
L 605 (Co-Cr-W-Ni alloy)	ASTM F90
LDPE	ASTM D1248
Radel	No Standard Applicable
Silicone	No Standard Applicable
Ultem	ASTM D5205

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Methods, Facilities and Controls

Method of Manufacturing

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Packaging

Humeral Stem

(b)(4)

The above listed materials are identical to those currently in use for Zimmer sterile implant packages with the only exception being that the configuration of the interior components correspond to the particular product being packaged.

Ulnar Stem

(b)(4)

The above listed materials are identical to those currently in use for Zimmer sterile implant packages with the only exception being that the configuration of the interior components correspond to the particular product being packaged.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Articulation Kit

(b)(4)

The above listed materials are identical to those currently in use for Zimmer sterile implant packages with the only exception being that the configuration of the interior components correspond to the particular product being packaged.

Humeral Screw Kit

(b)(4)

The above listed materials are identical to those currently in use for Zimmer sterile implant packages. Only the configuration of the interior components changes to correspond to the particular product being packaged.

Pyrogenicity

This device is not labeled as nonpyrogenic. Per USP XXIII (161), requirements for specified endotoxin levels do not apply to orthopaedic implants.

Latex

There is no natural latex rubber in this product or its packaging.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 6
2/27/13 email

zimmer

K123862
Zimmer Nexel Total Elbow
Refuse to Accept – Zimmer Response

FDA Question 1

			Yes	N/A	No
4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*		X		
	a.	Summary contains all elements per 21 CFR 807.92 See also 510(k) Summary Checklist			X
	b.	Statement contains all elements per 21 CFR 807.93			
	Comments: **The 510(k) summary is missing a complete Device Description, (lacking explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties) and is missing a comparison to predicate devices.**				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Zimmer Response to FDA Question 1

Please see Attachment 1 for a replacement 510(k) summary.

Within the device description section of the replacement 510(k) summary, the following verbiage was added to that of the original submission:

How the Device Functions: The Zimmer Nexel Total Elbow is an implant designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a constrained device assembly and consists of the following components: humeral component, ulnar component, humeral bearing-A, ulnar bearings-B, axle pin and humeral screws.

The Following Scientific Concepts, Design Features and Physical Properties form the Basis for the Zimmer Nexel Total Elbow: The humeral component has a humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal, an anterior flange designed to accept a bone graft and limit torsional and posterior migration, a humeral yoke with rounded corners to avoid the creation of stress risers within the medial and lateral humeral supracondylar columns, and plasma spray region to enhance fixation to bone cement within the medullary canal, and to improve fatigue strength. The ulnar component has an ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal, an ulnar eye that is both highly polished and nitrogen-enriched to limit wear of the apposing polymer bearings, and plasma spray region to enhance fixation to bone cement within the medullary canal. Bearings A and B are designed to broadly distribute joint reaction forces.

Materials Used: The humeral and ulnar components are made of a titanium alloy, the bearings A and B are made of Vitamin E highly cross-linked polyethylene, and the humeral screws and axle pin are made of a cobalt-chromium-molybdenum alloy.

Comparison to the Predicate: The proposed device (Zimmer Nexel Total Elbow) and the predicate device (Coonrad/Morrey Total Elbow) have the same intended use and similar indications for use. The proposed device humeral and ulnar components are very similar in terms of materials used and design/dimensions to the predicate device humeral and ulnar components. The primary differences between the proposed and predicate devices are that the proposed device bearing components are made of Vitamin E highly cross-linked polyethylene (the predicate device bearing components are made of ultra-high molecular-weight polyethylene), and the proposed device has bearings that articulate on both the outer and inner diameters of the ulnar eye (the predicate device has bearings that articulate on the inner diameter of the ulnar eye). Additionally, the proposed device uses screws and a 1-part axle pin to fix the bearings in place, while the predicate device uses a 2-part (snap-fit) axle pin.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Question 2

		Yes	N/A	No
17.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that due to potential differences in manufacturing that may not be known to the submitter, no identified differences does not necessarily mean that no performance testing is needed.*			X
	Comments: **The sponsor provides a tabulated comparison of the subject and predicate devices. From this tabulated list, it is clear there are differences between the subject and predicate devices with respect to indications for use and design features. The sponsor does not provide an analysis/discussion of why these differences do not render the device NSE.**			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Zimmer Response to FDA Question 2

Please see Attachment 2 for a replacement Substantial Equivalence Discussion.

Within the replacement Substantial Equivalence Discussion, the following verbiage was added to address FDA Question 2:

Why Any Differences Do Not Render the Device NSE

The major technological differences between the proposed device (Zimmer Nexel Total Elbow) and the predicate device (the Zimmer Coonrad/Morrey Total Elbow) are listed below along with the performance tests conducted to demonstrate substantial equivalence (the listed performance tests and their conclusions are described in more detail in *Section 18a Performance Testing – Bench* of this premarket notification submission):

Device Component	Major Difference Between Proposed and Predicate Devices	Performance Test Conducted to Demonstrate Substantial Equivalence
Humeral Component	- Distal design features for implant assembly - Plasma Spray	- Durability Testing (ZRR_WA_2542_12) - Modular Connection Fatigue Testing (ZRR_WA_2598_12) - Fatigue Testing (ZRR_WA_2554_12 & ZRR_WA_2589_12)
Ulnar Component	- Nitrogen enrichment	- Wear Testing (ZRR_WA_2407_11 & ZRR_WA_2552_12) - Fatigue Testing (ZRR_WA_2585_12, ZRR_WA_2615_12, ZRR_WA_2554_12 & ZRR_WA_2626_12)
Polyethylene Components	- Polyethylene material - Surfaces against which components are intended to articulate	- Wear Testing (ZRR_WA_2407_11 & ZRR_WA_2552_12) - Durability Testing (ZRR_WA_2542_12)
Axle Pin	- Single Solid vs. 2-Part Hollow construction	- Wear Testing (ZRR_WA_2407_11 & ZRR_WA_2552_12) - Durability Testing (ZRR_WA_2542_12) - Modular Connection Fatigue Testing (ZRR_WA_2598_12)
Humeral Screws	- Existence of screws	- Wear Testing (ZRR_WA_2407_11 & ZRR_WA_2552_12) - Durability Testing (ZRR_WA_2542_12) - Modular Connection Fatigue Testing (ZRR_WA_2598_12)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

K123862
Zimmer Nexel Total Elbow
Refuse to Accept – Zimmer Response

Current questions of safety and effectiveness (clinically observed failure modes) associated with elbow prostheses are humeral and ulnar component loosening, humeral and ulnar component fracture, polyethylene wear, system (implant assembly) durability and system (implant assembly) disassociation (also known as modular connection fatigue). To demonstrate that the proposed device is at least as safe and effective as the predicate device despite the compounding effects of these technological differences and previously outlined dimensional differences, fatigue (to assess resistance to fracture), wear, durability and modular connection fatigue performance tests were conducted (testing conclusions are described in more detail in *Section 18a Performance Testing – Bench* of this premarket notification submission). Stem loosening was not the focus of a performance test for the New Zimmer Total Elbow, because the variables (cementing technique, stem geometry, stem material and stem surface finish) associated with stem loosening are consistent from the predicate to the proposed device; and, therefore the proposed device (the New Zimmer Total Elbow) is expected to be as safe and effective as the predicate device (the Coonrad/Morrey Total Elbow) in terms of ability to resist stem loosening.

As reflected in the dFMEA documentation associated with the proposed device, the Zimmer Nexel Total Elbow does not raise any new/different types of questions of safety or effectiveness.

The proposed and predicate devices have the exact same intended use. The proposed and predicate devices share similar indications for use; where, the only changes in wording of the indications for use are that the proposed device has indications for use that are intended to add specificity to the indications for use of the proposed device. This added specificity does not change the intended meaning of the indications for use of the proposed device as compared to those of the predicate.

Because the aforementioned differences between the proposed and predicate devices do not constitute a new intended use, affect safety or effectiveness or raise different questions of safety and effectiveness, these differences *do not* render the proposed device NSE (not substantially equivalent).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Question 3

			Yes	N/A	No
27.	Assessment of the need for sterilization information				
	a.	Identification of device, and/or accessories, and/or components that are provided sterile.	X		
	b.	Identification of device, and/or accessories, and/or components that are end user sterilized			X
	Comments: **The sponsor has identified a number of patient contacting instruments; however, the sponsor has not discussed whether they are provided sterile or non-sterile and whether they are able to be cleaned and re-sterilized. Therefore, please provide 1) a discussion as to which components are end user sterilized and 2) instructions for cleaning and re-sterilization for these components.**				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Zimmer Response to FDA Question 3

Of the Class II Accessories to the Implant listed in Section 11a. (Device Description) of the premarket notification submission K123862, the following are provided non-sterile and are reusable and end-user sterilized (Table 1, below). Instructions for cleaning and re-sterilization of these instruments are provided in Attachment 3.

Catalog Number	Description
00-8401-002-00	T-Handle
00-8401-008-00	Reciprocating Saw Adapter
00-8401-008-01	Single Use Connector
00-8401-009-00	Slide Hammer
00-8401-018-00	Ulnar Bearing Tamp
00-8401-012-04	Trephine Stabilizer, Size 4
00-8401-012-05	Trephine Stabilizer, Size 5
00-8401-014-07	Ulnar Provisional, Size 4, 75 mm, Left
00-8401-014-11	Ulnar Provisional, Size 4, 115 mm, Left
00-8401-015-07	Ulnar Provisional, Size 5, 75 mm, Left
00-8401-015-11	Ulnar Provisional, Size 5, 115 mm, Left
00-8401-016-09	Ulnar Provisional, Size 6, 90 mm, Left
00-8401-016-11	Ulnar Provisional, Size 6, 115 mm, Left
00-8401-024-07	Ulnar Provisional, Size 4, 75 mm, Right
00-8401-024-11	Ulnar Provisional, Size 4, 115 mm, Right
00-8401-025-07	Ulnar Provisional, Size 5, 75 mm, Right
00-8401-025-11	Ulnar Provisional, Size 5, 115 mm, Right
00-8401-026-09	Ulnar Provisional, Size 6, 90 mm, Right
00-8401-026-11	Ulnar Provisional, Size 6, 115 mm, Right
00-8401-019-00	Articulation Inserter
00-8401-028-00	Ulnar Stem Inserter
00-8401-029-00	Implant Extractor Hook
00-8401-033-01	Ulnar Rasp, Pilot, Left
00-8401-033-02	Ulnar Rasp, Pilot, Right

Table 1 Class II Accessories to the Implant provided non-sterile and are reusable and end-user sterilized

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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00-8401-034-01	Ulnar Rasp, Size 4/5, Left
00-8401-034-02	Ulnar Rasp, Size 4/5, Right
00-8401-036-01	Ulnar Rasp, Size 6, Left
00-8401-036-02	Ulnar Rasp, Size 6, Right
00-8401-039-00	Ulnar Clearance Template
00-8401-044-10	Humeral Provisional, Size 4, 100 mm
00-8401-044-15	Humeral Provisional, Size 4, 150 mm
00-8401-045-10	Humeral Provisional, Size 5, 100 mm
00-8401-045-15	Humeral Provisional, Size 5, 150 mm
00-8401-046-10	Humeral Provisional, Size 6, 100 mm
00-8401-046-15	Humeral Provisional, Size 6, 150 mm
00-8401-055-15	Humeral Provisional, Long Flange, Size 5, 150mm
00-8401-055-20	Humeral Provisional, Long Flange, Size 5, 200mm
00-8401-056-15	Humeral Provisional, Long Flange, Size 6, 150mm
00-8401-056-20	Humeral Provisional, Long Flange, Size 6, 200mm
00-8401-058-04	Humeral Stem Inserter, Size 4
00-8401-058-05	Humeral Stem Inserter, Size 5/6
00-8401-059-04	Humeral Extractor Plate, Size 4
00-8401-059-05	Humeral Extractor Plate, Size 5/6
00-8401-060-00	Humeral Awl Reamer
00-8401-061-00	I/E Alignment Rod
00-8401-064-00	Humeral Rasp, Pilot
00-8401-064-10	Humeral Rasp, Size 4, 100 mm
00-8401-064-15	Humeral Rasp, Size 4, 150 mm
00-8401-065-10	Humeral Rasp, Size 5, 100 mm
00-8401-065-15	Humeral Rasp, Size 5, 150 mm
00-8401-066-10	Humeral Rasp, Size 6, 100 mm
00-8401-066-15	Humeral Rasp, Size 6, 150 mm
00-8401-070-45	Flexible Solid Reamer, 4.5 mm
00-8401-070-05	Flexible Solid Reamer, 5 mm

Table 1 (continued) Class II Accessories to the Implant provided non-sterile and are reusable and end-user sterilized

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

00-8401-072-01	Flexible Cannulated Reamer, 5.5 mm
00-8401-072-02	Flexible Cannulated Reamer, 6 mm
00-8401-072-03	Flexible Cannulated Reamer, 6.5 mm
00-8401-072-04	Flexible Cannulated Reamer, 7 mm
00-8401-072-05	Flexible Cannulated Reamer, 8 mm
00-8401-072-06	Flexible Cannulated Reamer, 9 mm
00-8401-072-07	Flexible Cannulated Reamer, 10 mm
00-8401-072-08	Flexible Cannulated Reamer, 11 mm
00-8401-072-09	Flexible Cannulated Reamer, 12 mm
00-8401-074-00	Trephine, Size 4
00-8401-075-00	Trephine, Size 5/6
00-8401-078-00	Humeral Bearing Driver
00-8401-079-00	Humeral Bearing Driver Pin
00-8401-081-00	Ulnar Bearing Assembly Tool
00-8401-082-00	Humeral Bearing Placement Tool
00-8401-084-00	Humeral Screw Holder, Size 4
00-8401-085-00	Humeral Screw Holder, Size 5/6
00-8401-089-00	Humeral Screw Removal Driver
00-8401-091-00	Humeral Bearing Extractor
00-8401-092-00	Articulation Extractor
00-8401-093-00	Humeral Extractor Screw
00-8401-097-00	Humeral Screw Removal Driver Bit
00-8401-004-00	Humeral Cut Guide, Size 4
00-8401-005-00	Humeral Cut Guide, Size 5/6

Table 1 (continued) Class II Accessories to the Implant provided non-sterile and are reusable and end-user sterilized

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Of the Class II Accessories to the Implant listed in Section 11a. (Device Description) of the premarket notification submission K123862, the following are provide sterile, are intended to be used during only one surgery (single use) and are not intended to be end-user sterilized (Table 2, below).

Catalog Number	Description	Sterilization Method	Radiation Dose	Validation Method	Sterility Assurance Level (SAL)
00-8401-088-00	Humeral Screw Installation Driver Bit	Gamma Irradiation	25.0-37.0 kGy	AAMI TIR33, VD_{MAX}^{20}	10^{-6} or better
00-8401-080-00	Torque-Limiting Humeral Screw Driver	Gamma Irradiation	25.0-40.0 kGy	AAMI 11137-2, VD_{MAX}^{25}	10^{-6} or better

Table 2 *Class II Accessories to the Implant provided sterile*

The Class II Accessories to the Implant (listed in Table 2, above) that are provided sterile are packaged as follows:

Humeral Screw Installation Driver Bit

(b)(4)

[redacted]

Torque-Limiting Humeral Screw Driver

(b)(4)

[redacted]

The above listed materials are identical to those currently in use for other similar sterile instrument packages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Question 4

			Yes	N/A	No
28.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*				
	a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	X		
	b.	A description of method to validate the sterilization cycle (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided	X		
	c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. Select "N/A" if not sterilized using chemical sterilants.			X
	d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package)	X		
	e.	Sterility Assurance Level (SAL) stated	X		
	f.	If device is blood-contacting, a permanent implant, or contacts cerebrospinal fluid, or device is labeled "non-pyrogenic," submission contains a description of the endotoxin method used to make a determination (e.g., LAL), endotoxin release specification (e.g., 20 EU/device), and a rationale for the specification. *Select "N/A" if device is not blood-contacting, not a permanent implant, does not contact cerebrospinal fluid, and is not labeled "non-pyrogenic." Select "N/A" if a rationale for omission is provided.*			X
	Comments: **(c) The sponsor has provided a promissory note for EO residuals. Please provide EO residuals remaining on the device following sterilization validation.** **(f) The sponsor does not provide a rationale for omission of Pyrogen Testing.**				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Zimmer Response to FDA Question 4

(c) As discussed during the 15 January 2013 phone conversation between Joanna Surma (Zimmer, Inc.) and Peter Allen (FDA), the EO residual data will be provided to Peter Allen via email following each of the following testing phases:

- EO Residuals after 1 Sterilization Cycle: expected by mid-February
- EO Residuals after 2 Sterilization Cycles: expected by early March
- EO Residuals after 3 Sterilization Cycles: expected by early- to mid-March

(f) Page 87 of the premarket notification submission K123862 stated the following rationale for omission of Pyrogen Testing (additionally, Zimmer makes no "pyrogen-free" or "non-pyrogenic" label claims):

> "This device is not labeled as nonpyrogenic. Per USP XXIII (161), requirements for specified endotoxin levels do not apply to orthopaedic implants."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

FDA Question 5

		Yes	N/A	No
32.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)			X
	Comments: **Sponsor does not state the contact classification for the instruments.**			

Zimmer Response to FDA Question 5

Of the Class II Accessories to the Implant listed in Section 11a. (Device Description) of the premarket notification submission K123862, all are *external communicating devices* contacting *tissue/bone* with *limited exposure* (less than 24 hour duration), according to definitions presented in Section 5 of ISO 10993-1.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Attachment 7
2/27/13 email

Predicate Device(s)

The predicate and design basis for the Zimmer Nexel Total Elbow (the proposed device) is the Coonrad/Morrey Total Elbow, manufactured by Zimmer. Clearance letters (K001989 and K053189 cleared 25 July 2000 and 9 December 2005, respectively) for the predicate device are included at the end of this section.

Similarities and differences between the proposed implants and the predicate implants are tabulated below.

Substantial Equivalence Comparison

Indications for Use

	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Intended Use	To be used in conjunction with bone cement to replace the articulating surfaces of the humeroulnar joint.	To be used in conjunction with bone cement to replace the articulating surfaces of the humeroulnar joint.
Indications for Use	• Elbow joint destruction which significantly compromises the activities of daily living • Post-traumatic lesions or bone loss contributing to elbow instability • Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis • Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain • Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis • Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus • Revision arthroplasty **CAUTION:** This device is intended for cemented use only.	• Elbow joint destruction which significantly compromises the activities of daily living • Post-traumatic lesions or bone loss contributing to elbow instability • Ankylosed joints, especially in cases of bilateral ankylosis from causes other than sepsis • Advanced rheumatoid or degenerative arthritis with incapacitating pain • Instability or loss of motion when the degree of joint damage precludes less radical procedures • Revision arthroplasty **CAUTION:** This device is intended for cemented use only.
Product Code	JDC	JDC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

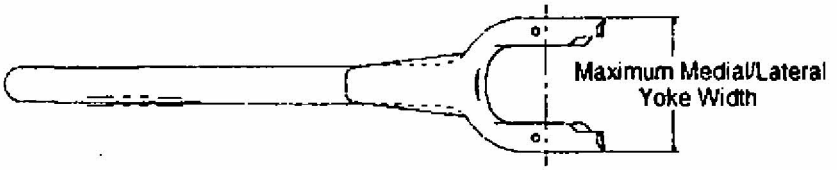
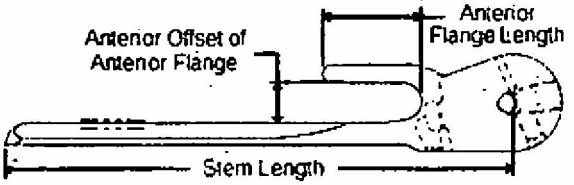
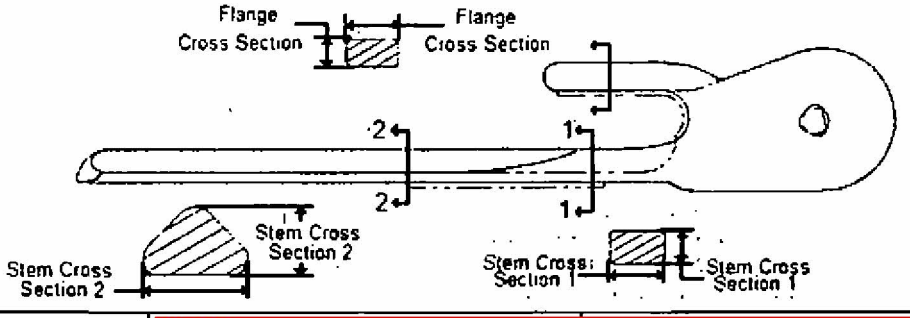
Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Technology

	Feature	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Humeral Component – General	**Material**	Wrought Tivanium Alloy (Ti-6Al-4V) with Titanium Plasma Spray	Wrought Tivanium Alloy (Ti-6Al-4V) with a porous coating of Titanium Beads
	Fixation Method	Intended for cemented use only	Intended for cemented use only
	Comparable Sizes	Size 4, Standard Flange, 100mm Size 4, Standard Flange, 150mm Size 5, Standard Flange, 100mm Size 5, Standard Flange, 150mm Size 5, Long Flange, 150mm Size 5, Long Flange, 200mm Size 6, Standard Flange, 100mm Size 6, Standard Flange, 150mm Size 6, Long Flange, 150mm Size 6, Long Flange, 200mm	→ Size Extra Small, Standard Flange, 4in → Size Extra Small, Standard Flange, 6in → Size Small, Standard Flange, 4in → Size Small, Standard Flange, 6in → Size Small, Long Flange, 6in → Size Small, Long Flange, 8in → Size Regular, Standard Flange, 4in → Size Regular, Standard Flange, 6in → Size Regular, Long Flange, 6in → Size Regular, Long Flange, 8in
	Sterility	Provided Sterile via Gamma Irradiation	Provided Sterile via Gamma Irradiation
	Design Features	• Humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal • Anterior flange designed to accept a bone graft and limit torsional and posterior migration • Humeral yoke with rounded corners to avoid the creation of stress risers within the medial and lateral humeral supracondylar columns • Plasma spray region to enhance fixation to bone cement within the medullary canal, and to improve fatigue strength • Features to accept Humeral Screws, Axle Pin and polymer Bearings A and B	• Humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal • Anterior flange designed to accept a bone graft and limit torsional and posterior migration • Humeral yoke with squared corners • Titanium Bead coating region to enhance fixation to bone cement within the medullary canal • Features to accept Axle Pin and polymer Bearings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

	Feature	Dimension: Proposed Device: The Zimmer Nevel Total Elbow	Dimension: Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Humeral Component – Dimensional Comparison			
	Max. M/L Yoke Width	(b)(4)	(b)(4)
			
	Ant. Flange Offset	(b)(4)	
	Flange Length		
	Stem Length		
			
	Flange Cross Section	(b)(4)	
	Stem Cross Section 2 (distal region)		
	Stem Cross Section 1 (plasma spray region)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Feature	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Ulnar Component – General	**Material**	Wrought Tivanium Alloy (Ti-6Al-4V) with Titanium Plasma Spray	Wrought Tivanium Alloy (Ti-6Al-4V) with Titanium Plasma Spray
	Fixation Method	Intended for cemented use only	Intended for cemented use only
	Comparable Sizes	Left, Size 4, 75mm → Left, Size 4, 115mm → Left, Size 5, 75mm → Left, Size 5, 115mm → Left, Size 6, 90mm → Left, Size 6, 115mm → Right, Size 4, 75mm → Right, Size 4, 115mm → Right, Size 5, 75mm → Right, Size 5, 115mm → Right, Size 6, 90mm → Right, Size 6, 115mm →	→ Left, Size Extra Small, Standard → Left, Size Extra Small, Long → Left, Size Small, Standard → Left, Size Small, Long → Left, Size Regular, Standard → Left, Size Regular, Long → Right, Size Extra Small, Standard → Right, Size Extra Small, Long → Right, Size Small, Standard → Right, Size Small, Long → Right, Size Regular, Standard → Right, Size Regular, Long
	Sterility	Provided Sterile via Gamma Irradiation	Provided Sterile via Gamma Irradiation
	Design Features	• Left and right side-specific • Ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal • Ulnar eye that is both highly polished and nitrogen-enriched to limit wear of the apposing polymer bearings • Plasma spray region to enhance fixation to bone cement within the medullary canal	• Left and right side-specific • Ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal • Ulnar eye that is highly polished to limit wear of the apposing polymer bearings • Plasma spray region to enhance fixation to bone cement within the medullary canal

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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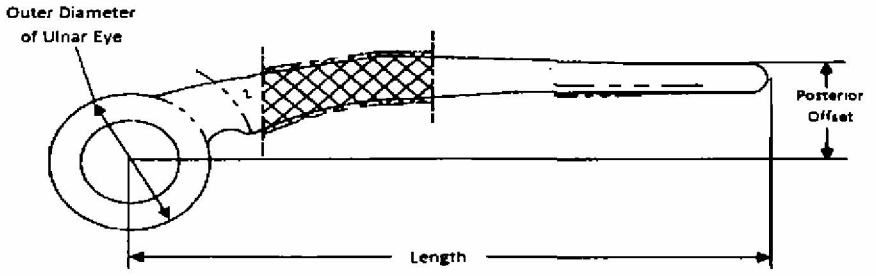
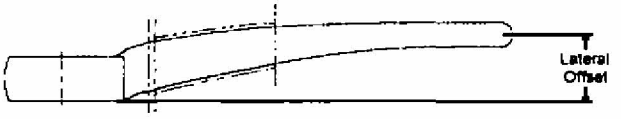
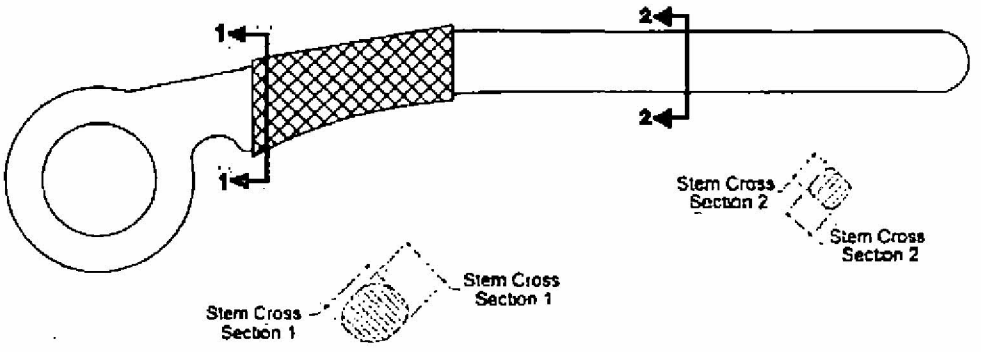
Ulnar Component – Dimensional Comparison

Feature	Dimension	
	Proposed Device: The Zimmer Novel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
		
OD of Ulnar Eye	(b)(4)	(b)(4)
Posterior Offset		
Stem Length		
		
Lateral Offset	(b)(4)	
		
Stem Cross Section 1 (plasma spray region)	(b)(4)	
Stem Cross Section 2		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Feature	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Polyethylene Components - General	Material	Vitamin E HXPE (Vitamin E Highly Cross-Linked Polyethylene)	UHMWPE (Ultra-High Molecular-Weight Polyethylene)
	Fixation Method	Press-Fit to Humeral Component	Sliding-Fit to Humeral Component Press-Fit to Ulnar Component
	Sterility	Provided Sterile via Ethylene Oxide	Provided Sterile via Gamma Irradiation
	Design Features	• Bearings A and B: - Designed to broadly distribute joint reaction forces - Designed to articulate against the Eye of the Ulnar Component - Features to allow for press-fit mate to Humeral Component • Bearings B only: - Features to allow for press-fit mate to Axle Pin - Designed to articulate against the inner-diameter and the medial and lateral surfaces of the Eye of the Ulnar Component • Bearing A only: - Designed to articulate against the outer-diameter of the Eye of the Ulnar Component	• Humeral Bushings: - Designed to articulate with the medial and lateral sides of the Eye of the Ulnar Component - Features to allow for sliding-fit mate to the Humeral Component and sliding-fit mate to the Axle Pin (also known as Hinge Pin, also known as Snap Pin) • Ulnar Bushing: - Features to allow for a press-fit mate with the Eye of the Ulnar Component - Designed to articulate against the Humeral Bushings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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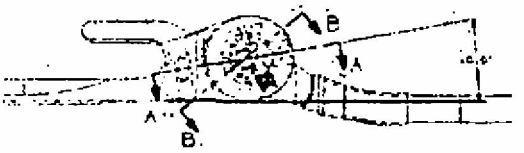
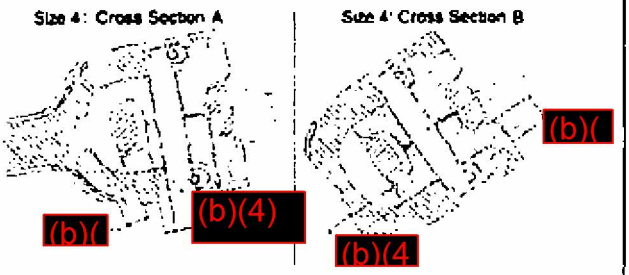
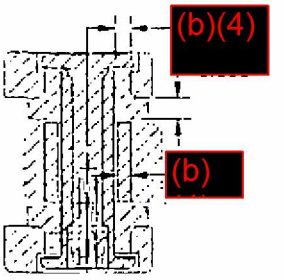
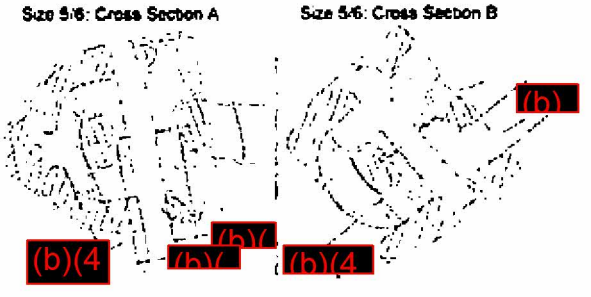
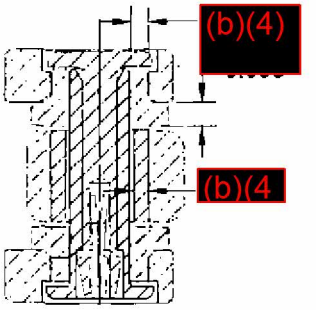
zimmer

Traditional 510(k)
Premarket Notification

	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Polyethylene Components - Sizes		
		
	Size 4 • Maximum Thickness of Proximal/Distal • Articulating Surfaces: (b)(• Minimum Thickness of Proximal/Distal • Articulating Surfaces: (b)(• Maximum Thickness of Medial/Lateral • Articulating Surfaces: (b)(• Minimum Thickness of Medial/Lateral • Articulating Surfaces: (b)(	Size Extra Small • Maximum Thickness of Proximal/Distal Articulating Surfaces: (b)(• Minimum Thickness of Proximal/Distal Articulating Surfaces: (b)(• Uniform Thickness of Medial/Lateral Articulating Surfaces: (b)(
		
	Size 5/6 • Maximum Thickness of Proximal/Distal • Articulating Surfaces: (b)(• Minimum Thickness of Proximal/Distal • Articulating Surfaces: (b)(• Maximum Thickness of Medial/Lateral • Articulating Surfaces: (b)(• Minimum Thickness of Medial/Lateral • Articulating Surfaces: (b)(	Size Small / Regular • Maximum Thickness of Proximal/Distal Articulating Surfaces: (b)(• Minimum Thickness of Proximal/Distal Articulating Surfaces: (b)(4 • Uniform Thickness of Medial/Lateral Articulating Surfaces: (b)(

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Feature	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Axle Pin	Material	Zimaloy (Cobalt-Chromium-Molybdenum Alloy)	Zimaloy (Cobalt-Chromium-Molybdenum Alloy)
	Fixation Method	• Press-Fit to Bearings B • Compression fit between the taper of the Humeral Screws and the yoke of the Humeral Component	• Sliding-Fit to Bearings • Snap-Fit between inner and outer Axle Pin components
	Sizes	Size 4 (b) Long Diameter • Solid Material Throughout Size 5/6 (b) Long Diameter • Solid Material Throughout	Size Extra Small (b) (4) Long Outer Diameter Wall Thickness Size Small/Regular (b)(4) Long Outer Diameter Wall Thickness
	Sterility	Provided Sterile via Ethylene Oxide	Provided Sterile via Gamma Irradiation
	Design Features	• Designed to remain in a fixed position (not translate nor rotate) throughout the entire *humeroulnar joint range of motion* • Machined complete as a single, solid component	• Designed to freely rotate and slide • Machined as 2 (an inner and an outer) hollow components that snap together intraoperatively
Humeral Screws	Material	Zimaloy (Cobalt-Chromium-Molybdenum Alloy)	Not Applicable: No comparable part in the predicate system
	Fixation Method	Threads engage with the Spiralock® threads of the Humeral Component	
	Sizes	Single size mates with all humeral component sizes and both axle pin sizes	
	Sterility	Provided Sterile via Gamma Irradiation	
	Design Features	• Designed to remain in a fixed position throughout the entire humeroulnar joint range of motion (not directly loaded by any compressive joint reaction force during flexion or extension of the humeroulnar joint) • Headless design intended to ensure the constant application of a clamp-load to the axle-pin and to avoid soft tissue impingement or irritation associated with a protruding screw head • Non-threaded taper to (along with the Humeral Component) hold Axle Pin in compression • Pilot feature to avoid cross-threading	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Constraint Characteristics		Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Constrained Range of Motion (defined in terms of Ulnar Component movement with respect to Humeral Component)	Varus/Valgus Angular Laxity		Neutral to Maximum Varus: (b) Neutral to Maximum Valgus: (b) Total Included Angle: (b)(	Neutral to Maximum Varus: (b)(Neutral to Maximum Valgus: 4.0 Total Included Angle: (b)
	Internal/External Rotational Laxity		Neutral to Maximum Internal Rotation: (b)(Neutral to Maximum External Rotation: (b)(Total Included Angle: (b	Neutral to Maximum Internal Rotation: (b) Neutral to Maximum External Rotation: (b) Total Included Angle: (b)
	Pistoning	Proximal/Distal Translational Laxity	Neutral to Maximum Proximal Neutral to Maximum Distal: Total Proximal/Distal Laxity:	Neutral to Maximum Proximal: Neutral to Maximum Distal: Total Proximal/Distal Laxity:
		Anterior/Posterior Translation Laxity	Neutral to Maximum Anterior: Neutral to Maximum Posterior: Total Anterior/Posterior Laxity	Neutral to Maximum Anterior: Neutral to Maximum Posterior: Total Anterior/Posterior Laxity:
	Medial/Lateral Translation Laxity		Neutral to Maximum Medial: Neutral to Maximum Lateral: Total Medial/Lateral Laxity:	Neutral to Maximum Medial: Neutral to Maximum Lateral: Total Medial/Lateral Laxity:
	Flexion/Extension Range (defined in terms of degrees flexion)		All Humeral and Ulnar combinations: (b)(4)	Humeral size XS with Ulnar size XS: (b)(4) Humeral size XS with Ulnar size S: (b)(4) Humeral size XS with Ulnar size REG: (b)(4) Humeral size S with Ulnar size XS: (b)(4) Humeral size S with Ulnar size S: (b)(4) Humeral size S with Ulnar size REG: (b)(4) Humeral size REG with Ulnar size XS: (b)(4) Humeral size REG with Ulnar size S: (b)(4) Humeral size REG with Ulnar size REG: (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Why Any Differences Do Not Render the Device NSE

The major technological differences between the proposed device (Zimmer Nexel Total Elbow) and the predicate device (the Zimmer Coonrad/Morrey Total Elbow) are listed below along with the performance tests conducted to demonstrate substantial equivalence (the listed performance tests and their conclusions are described in more detail in *Section 18a Performance Testing – Bench* of this premarket notification submission):

Device Component	Major Difference Between Proposed and Predicate Devices	Performance Test Conducted to Demonstrate Substantial Equivalence
Humeral Component	- Distal design features for implant assembly - Plasma Spray	- Durability Testing - Modular Connection Fatigue Testing - Fatigue Testing
Ulnar Component	- Nitrogen enrichment	- Wear Testing - Fatigue Testing
Polyethylene Components	- Polyethylene material - Surfaces against which components are intended to articulate	- Wear Testing - Durability Testing
Axle Pin	- Single Solid vs. 2-Part Hollow construction	- Wear Testing - Durability Testing - Modular Connection Fatigue Testing
Humeral Screws	- Existence of screws	- Wear Testing - Durability Testing - Modular Connection Fatigue Testing

Current questions of safety and effectiveness (clinically observed failure modes) associated with elbow prostheses are humeral and ulnar component loosening, humeral and ulnar component fracture, polyethylene wear, system (implant assembly) durability and system (implant assembly) disassociation (also known as modular connection fatigue). To demonstrate that the proposed device is at least as safe and effective as the predicate device despite the compounding effects of these technological differences and previously outlined dimensional differences, fatigue (to assess resistance to fracture), wear, durability and modular connection fatigue performance tests were conducted (testing conclusions are described in more detail in *Section 18a Performance*

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Testing – Bench of this premarket notification submission). Stem loosening was not the focus of a performance test for the New Zimmer Total Elbow, because the variables (cementing technique, stem geometry, stem material and stem surface finish) associated with stem loosening are consistent from the predicate to the proposed device; and, therefore the proposed device (the New Zimmer Total Elbow) is expected to be as safe and effective as the predicate device (the Coonrad/Morrey Total Elbow) in terms of ability to resist stem loosening.

As reflected in the dFMEA documentation associated with the proposed device, the Zimmer Nexel Total Elbow does not raise any new/different types of questions of safety or effectiveness.

The proposed and predicate devices have the exact same intended use. The proposed and predicate devices share similar indications for use; where, the only changes in wording of the indications for use are that the proposed device has indications for use that are intended to add specificity to the indications for use of the proposed device. This added specificity does not change the intended meaning of the indications for use of the proposed device as compared to those of the predicate.

Because the aforementioned differences between the proposed and predicate devices do not constitute a new intended use, affect safety or effectiveness or raise different questions of safety and effectiveness, these differences *do not* render the proposed device NSE (not substantially equivalent).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Performance Specifications

Test	Test Results	
	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Fatigue Testing: Humeral Stem (Plasma Spray Region)	Five Zimmer Nexel Total Elbow humeral stems achieved (b)(4) load cycles at (b)(without fracture.	The predicate device humeral component was fatigue tested at various load levels, and the fatigue strength at (b)(4) cycles was determined to be (b)(
Fatigue Testing: Ulnar Stem (Mid-Stem Region)	Five Zimmer Nexel Total Elbow ulnar stems achieved (b)(4) load cycles in the mid-stem region at a load of (b) without fracture.	The predicate device ulnar component was fatigue tested at various load levels, and the fatigue strength at (b)(4) load cycles in the mid-stem region was determined to be (b)(
Fatigue Testing: Ulnar Stem (Plasma Spray Region)	Five Zimmer Nexel Total Elbow ulnar stems achieved (b)(4) load cycles in the plasma spray region at a load of (b)(without fracture.	The predicate device ulnar component was fatigue tested at various load levels, and the fatigue strength at (b)(4) load cycles in the plasma spray region was determined to be (b)(
Wear Testing	The Zimmer Nexel Total Elbow mean gravimetric wear rate (b)(4) at (b)(4) load cycles) was 91% less than that of the predicate.	The predicate device mean gravimetric wear rate was (b)(4) load cycles.
Durability Testing	The Zimmer Nexel Total Elbow device achieved (b)(4) run-outs at an equivalent of (b)(weight-in-hand.	The run out load for the predicate device was found to be equivalent to (b) lbf weight-in-hand.
Modular Connection Fatigue Testing	The median fatigue strength of the non-articulating, mechanically locked, modular Zimmer Nexel Total Elbow implant components was no less than (b)(4)	Not Applicable: The Zimmer Coonrad/Morrey Total Elbow does not have non-articulating, mechanically-locked, modular implant components comparable to those of the proposed device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Allen, Peter

From: Jason Heckaman <Jason.Heckaman@zimmer.com>
Sent: Thursday, February 14, 2013 12:55 PM
To: Allen, Peter
Cc: Joanna L. Surma
Subject: RE: K123862
Attachments: 2013-02-14_Nexel Articulation Kit EO Residual Results.pdf

Hi Pete,

Please find enclosed EO residual data at 16 hours, 2-day, and 3-day time points following both one and two sterilization cycles. All results were within the specifications.

If there is anything else I can help you with, just let me know.

Kind Regards,
Jason

From: Jason Heckaman
Sent: Tuesday, February 12, 2013 10:58 AM
To: 'Allen, Peter'
Cc: Joanna L. Surma
Subject: RE: K123862

Hi Pete,

By the end of business Friday we expect to be able to provide you with EO residual data following both one and two sterilization cycles.

Kind Regards,
Jason

From: Jason Heckaman
Sent: Monday, February 11, 2013 5:10 PM
To: 'Allen, Peter'; Joanna L. Surma
Subject: RE: K123862

Hi Pete,

I will come back to you with an update by the end of the day tomorrow.

Kind Regards,
Jason

From: Allen, Peter [mailto:Peter.Allen@fda.hhs.gov]
Sent: Monday, February 11, 2013 2:21 PM
To: Joanna L. Surma
Cc: Jason Heckaman
Subject: RE: K123862

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Joanna/Jason,

I see that Joanna is out of the office this week, so Jason I am hoping you will be able to respond to this email ASAP. This is in regards to 510(k) submission K123862 – Zimmer Nexel Total Elbow.

Joanna had discussed the possibility of getting Ethylene Oxide residual testing results to me by mid-February. I need to know if these results will be available in the next week. Otherwise I will place this submission on hold until the results are available. Please let me know if you will be able to accommodate my request.

Thanks,

Pete

Peter G. Allen, MS
Biomedical Engineer
Joint Fixation One Branch (JFOB)
FDA/CDRH/ODE/DOD
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
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From: Joanna L. Surma [mailto:Joanna.Surma@zimmer.com]
Sent: Friday, February 08, 2013 9:19 AM
To: Allen, Peter
Cc: Jason Heckaman
Subject: K123862

Dear Mr. Allen,

I will be out of the office next week (10-15 Feb). Could you please copy my manager, Jason Heckaman, on any communications to me regarding K123862 (Zimmer Nexel Total Elbow) during that time?

Jason's email is Jason.Heckaman@Zimmer.com, and he can be reached by phone at 574.371.8675.

Thank you,
Joanna

Joanna L. Surma - MS, RAC
Associate Project Manager
Regulatory Affairs
Zimmer, Inc.
(o) 574.371.1642

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EO Residual Results

Zimmer Nexel™ Total Elbow Articulation Kit

Cycle + Timepoint	Analyte	Specification	Result
1X @ 16 hours	Ethylene Oxide (EO)	≤4mg/1st 24 hours	(b)(4)
		≤60mg/1st 30 days	
		≤2.5g lifetime	
		≤0.1 mg/day ADD*	
	Ethylene Chlorohydrin (ECH)	≤9mg/1st 24 hours	
		≤60mg/1st 30 days	
		≤10g lifetime	
		≤0.4 mg/day ADD	
	TCL** EO	≤10µg/cm^2	
	TCL ECH	≤5mg/cm^2	
1X @ Day 2	Ethylene Oxide (EO)	≤4mg/1st 24 hours	
		≤60mg/1st 30 days	
		≤2.5g lifetime	
		≤0.1 mg/day ADD	
	Ethylene Chlorohydrin (ECH)	≤9mg/1st 24 hours	
		≤60mg/1st 30 days	
		≤10g lifetime	
		≤0.4 mg/day ADD	
	TCL EO	≤10µg/cm^2	
	TCL ECH	≤5mg/cm^2	
1X @ Day 3	Ethylene Oxide (EO)	≤4mg/1st 24 hours	
		≤60mg/1st 30 days	
		≤2.5g lifetime	
		≤0.1 mg/day ADD	
	Ethylene Chlorohydrin (ECH)	≤9mg/1st 24 hours	
		≤60mg/1st 30 days	
		≤10g lifetime	
		≤0.4 mg/day ADD	
	TCL EO	≤10µg/cm^2	
	TCL ECH	≤5mg/cm^2	

*Average Daily Dose **Tolerable Contact Limit

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cycle + Timepoint	Analyte	Specification	Result
2X @ 16 hours	Ethylene Oxide (EO)	≤4mg/1st 24 hours	(b)(4)
		≤60mg/1st 30 days	
		≤2.5g lifetime	
		≤0.1 mg/day ADD*	
	Ethylene Chlorohydrin (ECH)	≤9mg/1st 24 hours	
		≤60mg/1st 30 days	
		≤10g lifetime	
		≤0.4 mg/day ADD	
	TCL** EO	≤10µg/cm^2	
	TCL ECH	≤5mg/cm^2	
2X @ Day 2	Ethylene Oxide (EO)	≤4mg/1st 24 hours	
		≤60mg/1st 30 days	
		≤2.5g lifetime	
		≤0.1 mg/day ADD	
	Ethylene Chlorohydrin (ECH)	≤9mg/1st 24 hours	
		≤60mg/1st 30 days	
		≤10g lifetime	
		≤0.4 mg/day ADD	
	TCL EO	≤10µg/cm^2	
	TCL ECH	≤5mg/cm^2	
2X @ Day 3	Ethylene Oxide (EO)	≤4mg/1st 24 hours	
		≤60mg/1st 30 days	
		≤2.5g lifetime	
		≤0.1 mg/day ADD	
	Ethylene Chlorohydrin (ECH)	≤9mg/1st 24 hours	
		≤60mg/1st 30 days	
		≤10g lifetime	
		≤0.4 mg/day ADD	
	TCL EO	≤10µg/cm^2	
	TCL ECH	≤5mg/cm^2	

*Average Daily Dose **Tolerable Contact Limit

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Allen, Peter

From: Joanna L. Surma <Joanna.Surma@zimmer.com>
Sent: Wednesday, January 16, 2013 11:05 AM
To: Allen, Peter
Subject: RE: K123862 - Refuse to Accept Notification - Zimmer Response
Attachments: C=20120101:2013=01=17 002.01:RTA.Response.pdf

Dear Mr. Allen,

Thank you for taking the time to call me yesterday to discuss the EO residual data availability timeline.

Within the attached RTA response, you'll find the following summary of that conversation:

> As discussed during the 15 January 2013 phone conversation between Joanna Surma (Zimmer, Inc.) and Peter Allen (FDA), the EO residual data will be provided to Peter Allen via email following each of the following testing phases:
>
> - EO Residuals after 1 Sterilization Cycle: expected by mid-February
> - EO Residuals after 2 Sterilization Cycles: expected by early March
> - EO Residuals after 3 Sterilization Cycles: expected by early- to mid-March

If you require any additional information or have any questions, please contact me by telephone (574.371.1642), email (Joanna.Surma@Zimmer) or fax (574.372.4605).

Sincerely,
Joanna

Joanna L. Surma - MS, RAC
Associate Project Manager
Regulatory Affairs
Zimmer, Inc.
(o) 574.371.1642
(c) 574.527.2361

From: Joanna L. Surma
Sent: Monday, January 14, 2013 8:40 PM
To: Allen, Peter
Cc: 'Hanley, Casey'
Subject: RE: K123862 - Refuse to Accept Notification

Dear Mr. Allen,

Thank you and Dr. Hanley for your feedback.

We have completed our response to your initial review of our submission for completeness, and would like to discuss the acceptability of a proposed timeline of availability for EO residuals (Acceptance Checklist Item 28c) via a 10-15minute phone conference before submitting the formal response.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please let me know you're availability Tuesday through Thursday this week for that phone conference, as we intend to send the formal response by Thursday 17 January 2013 to ensure its delivery to the FDA by 21 January 2013.

Sincerely,
Joanna

Joanna L. Surma - MS, RAC
Associate Project Manager
Regulatory Affairs
Zimmer, Inc.
(o) 574.371.1642
(c) 574.527.2361

From: Hanley, Casey [mailto:Casey.Hanley@fda.hhs.gov]
Sent: Friday, December 28, 2012 3:49 PM
To: Joanna L. Surma
Cc: Allen, Peter
Subject: K123862 - Refuse to Accept Notification

Dear Ms. Surma,

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K123862) Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness.

Please refer to the attached checklist and e-mail your response referencing the 510(k) number K123862 by January 21, 2013. Your response should address all of the elements identified as missing or inconsistent in the attached checklist. Failure to provide the requested information by January 21, 2013 may result in placing the file on hold.

Upon receipt of the requested information, FDA may have additional requests for information.

Please be advised that once our RTA policy is implemented, if your 510(k) submission does not meet the criteria established for administrative completeness, your file will not be accepted and we will not begin our substantive review until you submit the missing elements and your submission is accepted. Refer to the draft guidance document for information.

Should you have questions about this email, you may either contact me or Peter Allen, the lead reviewer assigned to your 510(k) submission.

Sincerely,
Casey

Casey L. Hanley, Ph.D.
U.S. Food and Drug Administration
CDRH/ODE/DOD/JFOB
10903 New Hampshire Ave
WO66 Room 1567
Silver Spring, MD 20993
Tel: (301)796 6948
casey.hanley@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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P.O. Box 708
Warsaw, IN 46581-0708
(574) 267-6131

17 January 2013

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Sir or Madam:

Subject: Additional Information – Zimmer Nexel Total Elbow – 510(k) (K123862)

Enclosed are Zimmer's responses to FDA's questions regarding the above-referenced submission.

If you require any additional information or have any questions, please contact me by telephone at (574) 371-1642, by e-mail at Joanna.Surma@Zimmer.com or by fax at (574) 372-4605.

Sincerely,

17 Jan 2013

Joanna L. Surma
Associate Project Manager, Regulatory Affairs

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Question 1

			Yes	N/A	No
4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*		X		
	a.	Summary contains all elements per 21 CFR 807.92 See also 510(k) Summary Checklist			X
	b.	Statement contains all elements per 21 CFR 807.93			
	Comments: **The 510(k) summary is missing a complete Device Description, (lacking explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties) and is missing a comparison to predicate devices.**				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Zimmer Response to FDA Question 1

Please see Attachment 1 for a replacement 510(k) summary.

Within the device description section of the replacement 510(k) summary, the following verbiage was added to that of the original submission:

How the Device Functions: The Zimmer Nexel Total Elbow is an implant designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a semi-constrained device assembly and consists of the following components: humeral component, ulnar component, humeral bearing-A, ulnar bearings-B, axle pin and humeral screws.

The Following Scientific Concepts, Design Features and Physical Properties form the Basis for the Zimmer Nexel Total Elbow: The humeral component has a humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal, an anterior flange designed to accept a bone graft and limit torsional and posterior migration, a humeral yoke with rounded corners to avoid the creation of stress risers within the medial and lateral humeral supracondylar columns, and plasma spray region to enhance fixation to bone cement within the medullary canal, and to improve fatigue strength. The ulnar component has an ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal, an ulnar eye that is both highly polished and nitrogen-enriched to limit wear of the apposing polymer bearings, and plasma spray region to enhance fixation to bone cement within the medullary canal. Bearings A and B are designed to broadly distribute joint reaction forces.

Materials Used: The humeral and ulnar components are made of a titanium alloy, the bearings A and B are made of Vitamin E highly cross-linked polyethylene, and the humeral screws and axle pin are made of a cobalt-chromium-molybdenum alloy.

Comparison to the Predicate: The proposed device (Zimmer Nexel Total Elbow) and the predicate device (Coonrad/Morrey Total Elbow) have the same intended use and similar indications for use. The proposed device humeral and ulnar components are very similar in terms of materials used and design/dimensions to the predicate device humeral and ulnar components. The primary differences between the proposed and predicate devices are that the proposed device bearing components are made of Vitamin E highly cross-linked polyethylene (the predicate device bearing components are made of ultra-high molecular-weight polyethylene), and the proposed device has bearings that articulate on both the outer and inner diameters of the ulnar eye (the predicate device has bearings that articulate on the inner diameter of the ulnar eye). Additionally, the proposed device uses screws and a 1-part axle pin to fix the bearings in place, while the predicate device uses a 2-part (snap-fit) axle pin.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Question 2

		Yes	N/A	No
17.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that due to potential differences in manufacturing that may not be known to the submitter, no identified differences does not necessarily mean that no performance testing is needed.*			X
	Comments: **The sponsor provides a tabulated comparison of the subject and predicate devices. From this tabulated list, it is clear there are differences between the subject and predicate devices with respect to indications for use and design features. The sponsor does not provide an analysis/discussion of why these differences do not render the device NSE.**			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Zimmer Response to FDA Question 2

Please see Attachment 2 for a replacement Substantial Equivalence Discussion.

Within the replacement Substantial Equivalence Discussion, the following verbiage was added to address FDA Question 2:

Why Any Differences Do Not Render the Device NSE

The major technological differences between the proposed device (Zimmer Nexel Total Elbow) and the predicate device (the Zimmer Coonrad/Morrey Total Elbow) are listed below along with the performance tests conducted to demonstrate substantial equivalence (the listed performance tests and their conclusions are described in more detail in *Section 18a Performance Testing – Bench* of this premarket notification submission):

Device Component	Major Difference Between Proposed and Predicate Devices	Performance Test Conducted to Demonstrate Substantial Equivalence
Humeral Component	- Distal design features for implant assembly - Plasma Spray	- Durability Testing (ZRR_WA_2542_12) - Modular Connection Fatigue Testing (ZRR_WA_2598_12) - Fatigue Testing (ZRR_WA_2554_12 & ZRR_WA_2589_12)
Ulnar Component	- Nitrogen enrichment	- Wear Testing (ZRR_WA_2407_11 & ZRR_WA_2552_12) - Fatigue Testing (ZRR_WA_2585_12, ZRR_WA_2615_12, ZRR_WA_2554_12 & ZRR_WA_2626_12)
Polyethylene Components	- Polyethylene material - Surfaces against which components are intended to articulate	- Wear Testing (ZRR_WA_2407_11 & ZRR_WA_2552_12) - Durability Testing (ZRR_WA_2542_12)
Axle Pin	- Single Solid vs. 2-Part Hollow construction	- Wear Testing (ZRR_WA_2407_11 & ZRR_WA_2552_12) - Durability Testing (ZRR_WA_2542_12) - Modular Connection Fatigue Testing (ZRR_WA_2598_12)
Humeral Screws	- Existence of screws	- Wear Testing (ZRR_WA_2407_11 & ZRR_WA_2552_12) - Durability Testing (ZRR_WA_2542_12) - Modular Connection Fatigue Testing (ZRR_WA_2598_12)

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Current questions of safety and effectiveness (clinically observed failure modes) associated with elbow prostheses are humeral and ulnar component loosening, humeral and ulnar component fracture, polyethylene wear, system (implant assembly) durability and system (implant assembly) disassociation (also known as modular connection fatigue). To demonstrate that the proposed device is at least as safe and effective as the predicate device despite the compounding effects of these technological differences and previously outlined dimensional differences, fatigue (to assess resistance to fracture), wear, durability and modular connection fatigue performance tests were conducted (testing conclusions are described in more detail in *Section 18a Performance Testing – Bench* of this premarket notification submission). Stem loosening was not the focus of a performance test for the New Zimmer Total Elbow, because the variables (cementing technique, stem geometry, stem material and stem surface finish) associated with stem loosening are consistent from the predicate to the proposed device; and, therefore the proposed device (the New Zimmer Total Elbow) is expected to be as safe and effective as the predicate device (the Coonrad/Morrey Total Elbow) in terms of ability to resist stem loosening.

As reflected in the dFMEA documentation associated with the proposed device, the Zimmer Nexel Total Elbow does not raise any new/different types of questions of safety or effectiveness.

The proposed and predicate devices have the exact same intended use. The proposed and predicate devices share similar indications for use; where, the only changes in wording of the indications for use are that the proposed device has indications for use that are intended to add specificity to the indications for use of the proposed device. This added specificity does not change the intended meaning of the indications for use of the proposed device as compared to those of the predicate.

Because the aforementioned differences between the proposed and predicate devices do not constitute a new intended use, affect safety or effectiveness or raise different questions of safety and effectiveness, these differences *do not* render the proposed device NSE (not substantially equivalent).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Question 3

			Yes	N/A	No
27.	Assessment of the need for sterilization information				
	a.	Identification of device, and/or accessories, and/or components that are provided sterile.	X		
	b.	Identification of device, and/or accessories, and/or components that are end user sterilized			X
	Comments: **The sponsor has identified a number of patient contacting instruments; however, the sponsor has not discussed whether they are provided sterile or non-sterile and whether they are able to be cleaned and re-sterilized. Therefore, please provide 1) a discussion as to which components are end user sterilized and 2) instructions for cleaning and re-sterilization for these components.**				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Zimmer Response to FDA Question 3

Of the Class II Accessories to the Implant listed in Section 11a. (Device Description) of the premarket notification submission K123862, the following are provided non-sterile and are reusable and end-user sterilized (Table 1, below). Instructions for cleaning and re-sterilization of these instruments are provided in Attachment 3.

Catalog Number	Description
00-8401-002-00	T-Handle
00-8401-008-00	Reciprocating Saw Adapter
00-8401-008-01	Single Use Connector
00-8401-009-00	Slide Hammer
00-8401-018-00	Ulnar Bearing Tamp
00-8401-012-04	Trephine Stabilizer, Size 4
00-8401-012-05	Trephine Stabilizer, Size 5
00-8401-014-07	Ulnar Provisional, Size 4, 75 mm, Left
00-8401-014-11	Ulnar Provisional, Size 4, 115 mm, Left
00-8401-015-07	Ulnar Provisional, Size 5, 75 mm, Left
00-8401-015-11	Ulnar Provisional, Size 5, 115 mm, Left
00-8401-016-09	Ulnar Provisional, Size 6, 90 mm, Left
00-8401-016-11	Ulnar Provisional, Size 6, 115 mm, Left
00-8401-024-07	Ulnar Provisional, Size 4, 75 mm, Right
00-8401-024-11	Ulnar Provisional, Size 4, 115 mm, Right
00-8401-025-07	Ulnar Provisional, Size 5, 75 mm, Right
00-8401-025-11	Ulnar Provisional, Size 5, 115 mm, Right
00-8401-026-09	Ulnar Provisional, Size 6, 90 mm, Right
00-8401-026-11	Ulnar Provisional, Size 6, 115 mm, Right
00-8401-019-00	Articulation Inserter
00-8401-028-00	Ulnar Stem Inserter
00-8401-029-00	Implant Extractor Hook
00-8401-033-01	Ulnar Rasp, Pilot, Left
00-8401-033-02	Ulnar Rasp, Pilot, Right

Table 1 Class II Accessories to the Implant provided non-sterile and are reusable and end-user sterilized

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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00-8401-034-01	Ulnar Rasp, Size 4/5, Left
00-8401-034-02	Ulnar Rasp, Size 4/5, Right
00-8401-036-01	Ulnar Rasp, Size 6, Left
00-8401-036-02	Ulnar Rasp, Size 6, Right
00-8401-039-00	Ulnar Clearance Template
00-8401-044-10	Humeral Provisional, Size 4, 100 mm
00-8401-044-15	Humeral Provisional, Size 4, 150 mm
00-8401-045-10	Humeral Provisional, Size 5, 100 mm
00-8401-045-15	Humeral Provisional, Size 5, 150 mm
00-8401-046-10	Humeral Provisional, Size 6, 100 mm
00-8401-046-15	Humeral Provisional, Size 6, 150 mm
00-8401-055-15	Humeral Provisional, Long Flange, Size 5, 150mm
00-8401-055-20	Humeral Provisional, Long Flange, Size 5, 200mm
00-8401-056-15	Humeral Provisional, Long Flange, Size 6, 150mm
00-8401-056-20	Humeral Provisional, Long Flange, Size 6, 200mm
00-8401-058-04	Humeral Stem Inserter, Size 4
00-8401-058-05	Humeral Stem Inserter, Size 5/6
00-8401-059-04	Humeral Extractor Plate, Size 4
00-8401-059-05	Humeral Extractor Plate, Size 5/6
00-8401-060-00	Humeral Awl Reamer
00-8401-061-00	I/E Alignment Rod
00-8401-064-00	Humeral Rasp, Pilot
00-8401-064-10	Humeral Rasp, Size 4, 100 mm
00-8401-064-15	Humeral Rasp, Size 4, 150 mm
00-8401-065-10	Humeral Rasp, Size 5, 100 mm
00-8401-065-15	Humeral Rasp, Size 5, 150 mm
00-8401-066-10	Humeral Rasp, Size 6, 100 mm
00-8401-066-15	Humeral Rasp, Size 6, 150 mm
00-8401-070-45	Flexible Solid Reamer, 4.5 mm
00-8401-070-05	Flexible Solid Reamer, 5 mm

Table 1 (continued) Class II Accessories to the Implant provided non-sterile and are reusable and end-user sterilized

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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00-8401-072-01	Flexible Cannulated Reamer, 5.5 mm
00-8401-072-02	Flexible Cannulated Reamer, 6 mm
00-8401-072-03	Flexible Cannulated Reamer, 6.5 mm
00-8401-072-04	Flexible Cannulated Reamer, 7 mm
00-8401-072-05	Flexible Cannulated Reamer, 8 mm
00-8401-072-06	Flexible Cannulated Reamer, 9 mm
00-8401-072-07	Flexible Cannulated Reamer, 10 mm
00-8401-072-08	Flexible Cannulated Reamer, 11 mm
00-8401-072-09	Flexible Cannulated Reamer, 12 mm
00-8401-074-00	Trephine, Size 4
00-8401-075-00	Trephine, Size 5/6
00-8401-078-00	Humeral Bearing Driver
00-8401-079-00	Humeral Bearing Driver Pin
00-8401-081-00	Ulnar Bearing Assembly Tool
00-8401-082-00	Humeral Bearing Placement Tool
00-8401-084-00	Humeral Screw Holder, Size 4
00-8401-085-00	Humeral Screw Holder, Size 5/6
00-8401-089-00	Humeral Screw Removal Driver
00-8401-091-00	Humeral Bearing Extractor
00-8401-092-00	Articulation Extractor
00-8401-093-00	Humeral Extractor Screw
00-8401-097-00	Humeral Screw Removal Driver Bit
00-8401-004-00	Humeral Cut Guide, Size 4
00-8401-005-00	Humeral Cut Guide, Size 5/6

Table 1 (continued) Class II Accessories to the Implant provided non-sterile and are reusable and end-user sterilized

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Of the Class II Accessories to the Implant listed in Section 11a. (Device Description) of the premarket notification submission K123862, the following are provide sterile, are intended to be used during only one surgery (single use) and are not intended to be end-user sterilized (Table 2, below).

Catalog Number	Description	Sterilization Method	Radiation Dose	Validation Method	Sterility Assurance Level (SAL)
00-8401-088-00	Humeral Screw Installation Driver Bit	Gamma Irradiation	(b)(4)	AAMI TIR33, VD_{MAX}^{20}	10^{-6} or better
00-8401-080-00	Torque-Limiting Humeral Screw Driver	Gamma Irradiation		AAMI 11137-2, VD_{MAX}^{25}	10^{-6} or better

Table 2 Class II Accessories to the Implant provided sterile

The Class II Accessories to the Implant (listed in Table 2, above) that are provided sterile are packaged as follows:

Humeral Screw Installation Driver Bit

(b)(4)

The above listed materials are identical to those currently in use for Zimmer sterile instrument packages. Only the configuration of the interior components changes to correspond to the particular product being packaged.

Torque-Limiting Humeral Screw Driver

(b)(4)

The above listed materials are identical to those currently in use for other similar sterile instrument packages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA Question 4

			Yes	N/A	No
28.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*				
	a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	X		
	b.	A description of method to validate the sterilization cycle (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided	X		
	c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. Select "N/A" if not sterilized using chemical sterilants.			X
	d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package)	X		
	e.	Sterility Assurance Level (SAL) stated	X		
	f.	If device is blood-contacting, a permanent implant, or contacts cerebrospinal fluid, or device is labeled "non-pyrogenic," submission contains a description of the endotoxin method used to make a determination (e.g., LAL), endotoxin release specification (e.g., 20 EU/device), and a rationale for the specification. *Select "N/A" if device is not blood-contacting, not a permanent implant, does not contact cerebrospinal fluid, and is not labeled "non-pyrogenic." Select "N/A" if a rationale for omission is provided.*			X
	Comments: **(c) The sponsor has provided a promissory note for EO residuals. Please provide EO residuals remaining on the device following sterilization validation.** **(f) The sponsor does not provide a rationale for omission of Pyrogen Testing.**				

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Zimmer Response to FDA Question 4

(c) As discussed during the 15 January 2013 phone conversation between Joanna Surma (Zimmer, Inc.) and Peter Allen (FDA), the EO residual data will be provided to Peter Allen via email following each of the following testing phases:

- EO Residuals after 1 Sterilization Cycle: expected by mid-February
- EO Residuals after 2 Sterilization Cycles: expected by early March
- EO Residuals after 3 Sterilization Cycles: expected by early- to mid-March

(f) Page 87 of the premarket notification submission K123862 stated the following rationale for omission of Pyrogen Testing (additionally, Zimmer makes no "pyrogen-free" or "non-pyrogenic" label claims):

> "This device is not labeled as nonpyrogenic. Per USP XXIII (161), requirements for specified endotoxin levels do not apply to orthopaedic implants."

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FDA Question 5

		Yes	N/A	No
32.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)			X
	Comments: **Sponsor does not state the contact classification for the instruments.**			

Zimmer Response to FDA Question 5

Of the Class II Accessories to the Implant listed in Section 11a. (Device Description) of the premarket notification submission K123862, all are *external communicating devices* contacting *tissue/bone* with *limited exposure* (less than 24 hour duration), according to definitions presented in Section 5 of ISO 10993-1.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Joanna L. Surma Associate Project Manager, Regulatory Affairs Telephone: (574) 371-1642 Fax: (574) 372-4605
Date:	13 December 2012
Trade Name:	Zimmer Nexel Total Elbow
Common Name:	Total Elbow Prosthesis
Classification Name and Reference:	Prosthesis, Elbow, Constrained, Cemented 21 CFR § 888.3150
Product Code:	JDC
Predicate Device:	Coonrad/Morrey Total Elbow, manufactured by Zimmer, K001989, cleared 25 July 2000 Coonrad/Morrey Total Elbow, manufactured by Zimmer, K053189, cleared 9 December 2005
Device Description:	The Zimmer Nexel total Elbow is a total elbow prosthesis designed for use with bone cement. It is available in multiple sizes and in right and left configurations. **How the Device Functions:** The Zimmer Nexel Total Elbow is an implant designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a semi-constrained device assembly and consists of the following components: humeral component, ulnar component, humeral bearing-A, ulnar bearings-B, axle pin and humeral screws. **The Following Scientific Concepts, Design Features and Physical Properties form the Basis for the Zimmer Nexel Total Elbow:** The humeral component has a humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal, an anterior flange designed to accept a

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bone graft and limit torsional and posterior migration, a humeral yoke with rounded corners to avoid the creation of stress risers within the medial and lateral humeral supracondylar columns, and plasma spray region to enhance fixation to bone cement within the medullary canal, and to improve fatigue strength. The ulnar component has an ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal, an ulnar eye that is both highly polished and nitrogen-enriched to limit wear of the apposing polymer bearings, and plasma spray region to enhance fixation to bone cement within the medullary canal. Bearings A and B are designed to broadly distribute joint reaction forces.

Materials Used: The humeral and ulnar components are made of a titanium alloy, the bearings A and B are made of Vitamin E highly cross-linked polyethylene, and the humeral screws and axle pin are made of a cobalt-chromium-molybdenum alloy.

Comparison to the Predicate: The proposed device (Zimmer Nexel Total Elbow) and the predicate device (Coonrad/Morrey Total Elbow) have the same intended use and similar indications for use. The proposed device humeral and ulnar components are very similar in terms of materials used and design/dimensions to the predicate device humeral and ulnar components. The primary differences between the proposed and predicate devices are that the proposed device bearing components are made of Vitamin E highly cross-linked polyethylene (the predicate device bearing components are made of ultra-high molecular-weight polyethylene), and the proposed device has bearings that articulate on both the outer and inner diameters of the ulnar eye (the predicate device has bearings that articulate on the inner diameter of the ulnar eye). Additionally, the proposed device uses screws and a 1-part axle pin to fix the bearings in place, while the predicate device uses a 2-part (snap-fit) axle pin.

Intended Use:
Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

Caution: This device is intended for cemented use only.

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510(k) Summary of Safety and Effectiveness – Zimmer Nexel Total Elbow

Comparison to Predicate Device:

The Zimmer Nexel Total Elbow is substantially equivalent to the predicate device in terms of form and function. The Zimmer Nexel Total Elbow and the predicate device share similar intended uses and indications for use.

Performance Data:

Non-Clinical Performance Testing Conducted:

- Stem Fatigue Testing
- Wear Testing
- Durability Testing
- Modular Connection Fatigue Testing

Non-Clinical Performance Testing Conclusions:

Non-clinical testing demonstrated that the New Zimmer Total Elbow meets performance requirements as defined by Design Control activities and is substantially equivalent to the predicate device in terms of safety and efficacy.

In this case, clinical data and conclusions were not needed to demonstrate substantial equivalence.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT 2

Predicate Device(s)

The predicate and design basis for the Zimmer Nexel Total Elbow (the proposed device) is the Coonrad/Morrey Total Elbow, manufactured by Zimmer. Clearance letters (K001989 and K053189 cleared 25 July 2000 and 9 December 2005, respectively) for the predicate device are included at the end of this section.

Similarities and differences between the proposed implants and the predicate implants are tabulated below.

Substantial Equivalence Comparison

Indications for Use

	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Intended Use	To be used in conjunction with bone cement to replace the articulating surfaces of the humeroulnar joint.	To be used in conjunction with bone cement to replace the articulating surfaces of the humeroulnar joint.
Indications for Use	• Elbow joint destruction which significantly compromises the activities of daily living • Post-traumatic lesions or bone loss contributing to elbow instability • Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis • Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain • Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis • Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus • Revision arthroplasty **CAUTION:** This device is intended for cemented use only.	• Elbow joint destruction which significantly compromises the activities of daily living • Post-traumatic lesions or bone loss contributing to elbow instability • Ankylosed joints, especially in cases of bilateral ankylosis from causes other than sepsis • Advanced rheumatoid or degenerative arthritis with incapacitating pain • Instability or loss of motion when the degree of joint damage precludes less radical procedures • Revision arthroplasty **CAUTION:** This device is intended for cemented use only.
Product Code	JDC	JDC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Technology

	Feature	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Conrad/Morrey Total Elbow (K001918, K053189)
Humeral Component – General	**Material**	Wrought Tivanium Alloy (Ti-6Al-4V) with Titanium Plasma Spray	Wrought Tivanium Alloy (Ti-6Al-4V) with a porous coating of Titanium Beads
	Fixation Method	Intended for cemented use only	Intended for cemented use only
	Comparable Sizes	Size 4, Standard Flange, 100mm →→→ Size 4, Standard Flange, 150mm →→→ Size 5, Standard Flange, 100mm →→→ Size 5, Standard Flange, 150mm →→→ Size 5, Long Flange, 150mm→→→→→ Size 5, Long Flange, 200mm→→→→→ Size 6, Standard Flange, 100mm →→→ Size 6, Standard Flange, 150mm →→→ Size 6, Long Flange, 150mm→→→→→ Size 6, Long Flange, 200mm→→→→→	→ Size Extra Small, Standard Flange, 4in → Size Extra Small, Standard Flange, 6in → Size Small, Standard Flange, 4in → Size Small, Standard Flange, 6in → Size Small, Long Flange, 6in → Size Small, Long Flange, 8in → Size Regular, Standard Flange, 4in → Size Regular, Standard Flange, 6in → Size Regular, Long Flange, 6in → Size Regular, Long Flange, 8in
	Sterility	Provided Sterile via Gamma Irradiation	Provided Sterile via Gamma Irradiation
	Design Features	• Humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal • Anterior flange designed to accept a bone graft and limit torsional and posterior migration • Humeral yoke with rounded corners to avoid the creation of stress risers within the medial and lateral humeral supracondylar columns • Plasma spray region to enhance fixation to bone cement within the medullary canal, and to improve fatigue strength • Features to accept Humeral Screws, Axle Pin and polymer Bearings A and B	• Humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal • Anterior flange designed to accept a bone graft and limit torsional and posterior migration • Humeral yoke with squared corners • Titanium Bead coating region to enhance fixation to bone cement within the medullary canal • Features to accept Axle Pin and polymer Bearings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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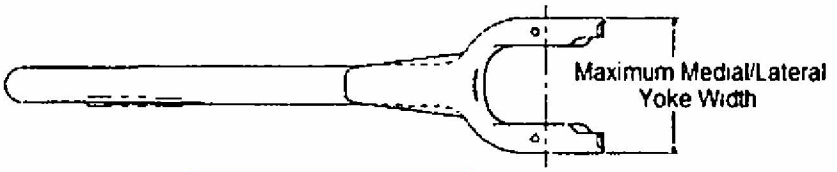
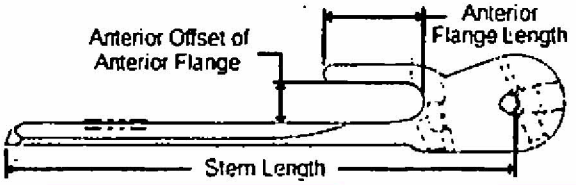
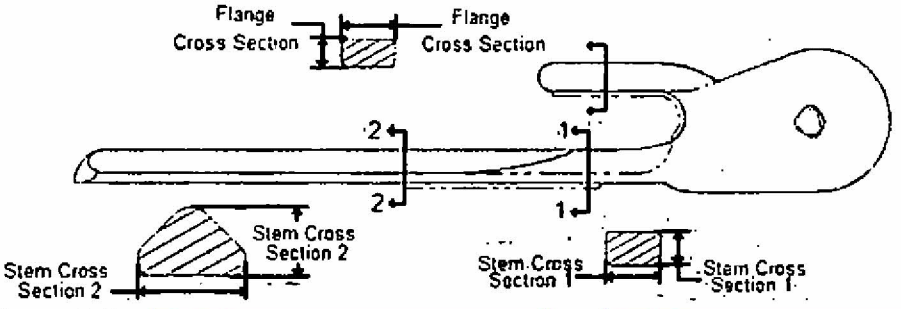
Humeral Component – Dimensional Comparison

Feature	Dimension	
	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
		
Max. M/L Yoke Width	(b)(4)	(b)(4)
		
Ant. Flange Offset	(b)(4)	(b)(4)
Flange Length		
Stem Length		
		
Flange Cross Section	(b)(4)	(b)(4)
Stem Cross Section 2 (distal region)		
Stem Cross Section 1 (plasma spray region)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Feature	Proposed Device: The Zimmer Nevel Total Elbow	Predicate Device: The Conrad/Morrey Total Elbow (K001918, K053189)
Ulnar Component – General	**Material**	Wrought Tivanium Alloy (Ti-6Al-4V) with Titanium Plasma Spray	Wrought Tivanium Alloy (Ti-6Al-4V) with Titanium Plasma Spray
	Fixation Method	Intended for cemented use only	Intended for cemented use only
	Comparable Sizes	Left, Size 4, 75mm Left, Size 4, 115mm Left, Size 5, 75mm Left, Size 5, 115mm Left, Size 6, 90mm Left, Size 6, 115mm Right, Size 4, 75mm Right, Size 4, 115mm Right, Size 5, 75mm Right, Size 5, 115mm Right, Size 6, 90mm Right, Size 6, 115mm	→ Left, Size Extra Small, Standard → Left, Size Extra Small, Long → Left, Size Small, Standard → Left, Size Small, Long → Left, Size Regular, Standard → Left, Size Regular, Long → Right, Size Extra Small, Standard → Right, Size Extra Small, Long → Right, Size Small, Standard → Right, Size Small, Long → Right, Size Regular, Standard → Right, Size Regular, Long
	Sterility	Provided Sterile via Gamma Irradiation	Provided Sterile via Gamma Irradiation
	Design Features	• Left and right side-specific • Ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal • Ulnar eye that is both highly polished and nitrogen-enriched to limit wear of the apposing polymer bearings • Plasma spray region to enhance fixation to bone cement within the medullary canal	• Left and right side-specific • Ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal • Ulnar eye that is highly polished to limit wear of the apposing polymer bearings • Plasma spray region to enhance fixation to bone cement within the medullary canal

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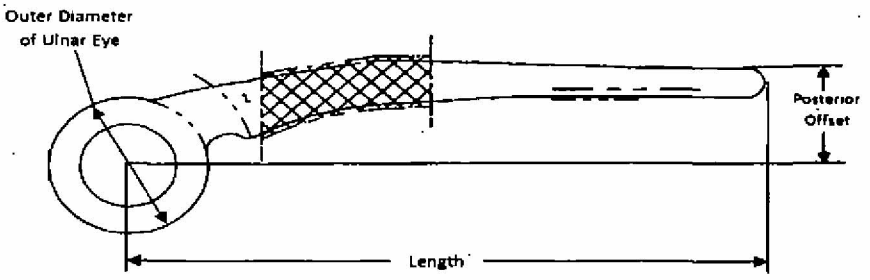
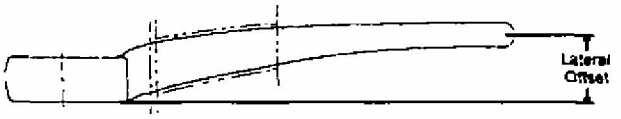
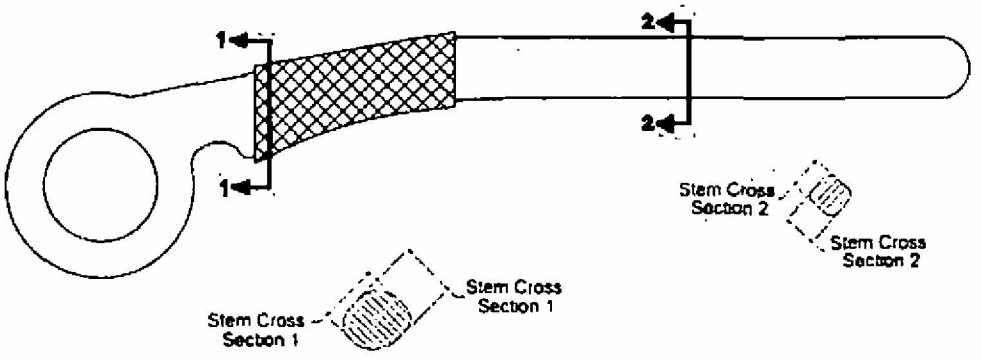
Feature	Dimension	
	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Ulnar Component – Dimensional Comparison		
		
OD of Ulnar Eye	(b)(4)	
Posterior Offset		
Stem Length		
		
Lateral Offset	(b)(4)	
		
Stem Cross Section 1 (plasma spray region)	(b)(4)	
Stem Cross Section 2		

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	Feature	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Polyethylene Components - General	Material	Vitamin E HXPE (Vitamin E Highly Cross-Linked Polyethylene)	UHMWPE (Ultra-High Molecular-Weight Polyethylene)
	Fixation Method	Press-Fit to Humeral Component	Sliding-Fit to Humeral Component Press-Fit to Ulnar Component
	Sterility	Provided Sterile via Ethylene Oxide	Provided Sterile via Gamma Irradiation
	Design Features	• Bearings A and B: - Designed to broadly distribute joint reaction forces - Designed to articulate against the Eye of the Ulnar Component - Features to allow for press-fit mate to Humeral Component • Bearings B only: - Features to allow for press-fit mate to Axle Pin - Designed to articulate against the inner-diameter and the medial and lateral surfaces of the Eye of the Ulnar Component • Bearing A only: - Designed to articulate against the outer-diameter of the Eye of the Ulnar Component	• Humeral Bushings: - Designed to articulate with the medial and lateral sides of the Eye of the Ulnar Component - Features to allow for sliding-fit mate to the Humeral Component and sliding-fit mate to the Axle Pin (also known as Hinge Pin, also known as Snap Pin) • Ulnar Bushing: - Features to allow for a press-fit mate with the Eye of the Ulnar Component - Designed to articulate against the Humeral Bushings

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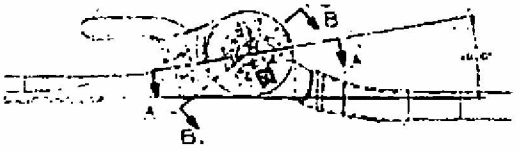
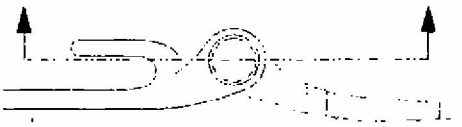
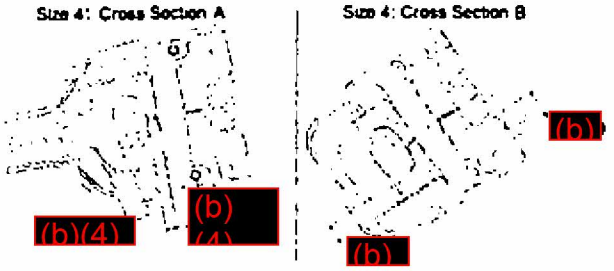
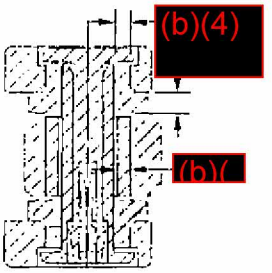
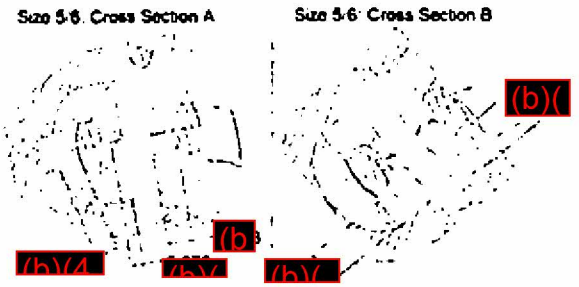
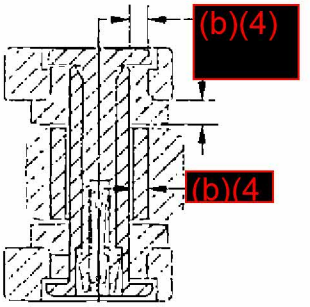
	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Polyethylene Components - Sizes		
		
	Size 4 • Maximum Thickness of Proximal/Distal Articulating Surfaces: (b)(4) • Minimum Thickness of Proximal/Distal Articulating Surfaces: (b)(4) • Maximum Thickness of Medial/Lateral Articulating Surfaces: (b)(4) • Minimum Thickness of Medial/Lateral Articulating Surfaces: (b)(4)	Size Extra Small • Maximum Thickness of Proximal/Distal Articulating Surfaces: (b)(4) • Minimum Thickness of Proximal/Distal Articulating Surfaces: (b)(4) • Uniform Thickness of Medial/Lateral Articulating Surfaces: (b)(4)
		
	Size 5/6 • Maximum Thickness of Proximal/Distal Articulating Surfaces: (b)(4) • Minimum Thickness of Proximal/Distal Articulating Surfaces: (b)(4) • Maximum Thickness of Medial/Lateral Articulating Surfaces: (b)(4) • Minimum Thickness of Medial/Lateral Articulating Surfaces: (b)(4)	Size Small / Regular • Maximum Thickness of Proximal/Distal Articulating Surfaces: (b)(4) • Minimum Thickness of Proximal/Distal Articulating Surfaces: (b)(4) • Uniform Thickness of Medial/Lateral Articulating Surfaces: (b)(4)

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	Feature	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Axle Pin	Material	Zimaloy (Cobalt-Chromium-Molybdenum Alloy)	Zimaloy (Cobalt-Chromium-Molybdenum Alloy)
	Fixation Method	• Press-Fit to Bearings B • Compression fit between the taper of the Humeral Screws and the yoke of the Humeral Component	• Sliding-Fit to Bearings • Snap-Fit between inner and outer Axle Pin components
	Sizes	Size 4 (b)(4) Long Diameter • Solid Material Throughout Size 5/6 (b)(4) Long Diameter • Solid Material Throughout	Size Extra Small (b)(4) Long Outer Diameter Wall Thickness Size Small/Regular (b)(4) Long Outer Diameter Wall Thickness
	Sterility	Provided Sterile via Ethylene Oxide	Provided Sterile via Gamma Irradiation
	Design Features	• Designed to remain in a fixed position (not translate nor rotate) throughout the entire humeroulnar joint range of motion • Machined complete as a single, solid component	• Designed to freely rotate and slide • Machined as 2 (an inner and an outer) hollow components that snap together intraoperatively
Humeral Screws	Material	Zimaloy (Cobalt-Chromium-Molybdenum Alloy)	Not Applicable: No comparable part in the predicate system
	Fixation Method	Threads engage with the Spiralock® threads of the Humeral Component	
	Sizes	Single size mates with all humeral component sizes and both axle pin sizes	
	Sterility	Provided Sterile via Gamma Irradiation	
	Design Features	• Designed to remain in a fixed position throughout the entire humeroulnar joint range of motion (not directly loaded by any compressive joint reaction force during flexion or extension of the humeroulnar joint) • Headless design intended to ensure the constant application of a clamp-load to the axle-pin and to avoid soft tissue impingement or irritation associated with a protruding screw head • Non-threaded taper to (along with the Humeral Component) hold Axle Pin in compression • Pilot feature to avoid cross-threading	

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	Semi-Constraint Characteristics		Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Semi-Constrained Range of Motion (defined in terms of Ulnar Component movement with respect to Humeral Component)	Varus/Valgus Angular Laxity		Neutral to Maximum Varus: (b) Neutral to Maximum Valgus: (b) Total Included Angle: (b)	Neutral to Maximum Varus: (b)(Neutral to Maximum Valgus: (b)(Total Included Angle: (b)
	Internal/External Rotational Laxity		Neutral to Maximum Internal Rotation: (b) Neutral to Maximum External Rotation: (b) Total Included Angle: (b)(	Neutral to Maximum Internal Rotation: (b)(Neutral to Maximum External Rotation: (b)(4 Total Included Angle: (b)(
	Pistoning	Proximal/Distal Translational Laxity	Neutral to Maximum Proximal (b)(4) Neutral to Maximum Distal: Total Proximal/Distal Laxity:	Neutral to Maximum Proximal (b)(4) Neutral to Maximum Distal: Total Proximal/Distal Laxity:
		Anterior/Posterior Translation Laxity	Neutral to Maximum Anterior: Neutral to Maximum Posterior Total Anterior/Posterior Laxity	Neutral to Maximum Anterior: Neutral to Maximum Posterior Total Anterior/Posterior Laxity
	Medial/Lateral Translation Laxity		Neutral to Maximum Medial: Neutral to Maximum Lateral: Total Medial/Lateral Laxity:	Neutral to Maximum Medial: Neutral to Maximum Lateral: Total Medial/Lateral Laxity:
	Flexion/Extension Range (defined in terms of degrees flexion)		All Humeral and Ulnar combinations: (b)(4)	Humeral size XS with Ulnar size XS: (b)(4) Humeral size XS with Ulnar size S: (b)(4) Humeral size XS with Ulnar size REG: (b)(4) Humeral size S with Ulnar size XS: (b)(4) Humeral size S with Ulnar size S: (b)(4) Humeral size S with Ulnar size REG: (b)(4) Humeral size REG with Ulnar size XS: (b)(4) Humeral size REG with Ulnar size S: (b)(4) Humeral size REG with Ulnar size REG: (b)(4)

Greater allowable translation would be a wear concern, durability issue. This can and was addressed in bench testing.

Is this a concern? constraint, stability, loosening? stress, fracture?

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Why Any Differences Do Not Render the Device NSE

The major technological differences between the proposed device (Zimmer Nexel Total Elbow) and the predicate device (the Zimmer Coonrad/Morrey Total Elbow) are listed below along with the performance tests conducted to demonstrate substantial equivalence (the listed performance tests and their conclusions are described in more detail in *Section 18a Performance Testing – Bench* of this premarket notification submission):

Device Component	Major Difference Between Proposed and Predicate Devices	Performance Test Conducted to Demonstrate Substantial Equivalence
Humeral Component	- Distal design features for implant assembly - Plasma Spray	- Durability Testing - Modular Connection Fatigue Testing - Fatigue Testing
Ulnar Component	- Nitrogen enrichment	- Wear Testing - Fatigue Testing
Polyethylene Components	- Polyethylene material - Surfaces against which components are intended to articulate	- Wear Testing - Durability Testing
Axle Pin	- Single Solid vs. 2-Part Hollow construction	- Wear Testing - Durability Testing - Modular Connection Fatigue Testing
Humeral Screws	- Existence of screws	- Wear Testing - Durability Testing - Modular Connection Fatigue Testing

Current questions of safety and effectiveness (clinically observed failure modes) associated with elbow prostheses are humeral and ulnar component loosening, humeral and ulnar component fracture, polyethylene wear, system (implant assembly) durability and system (implant assembly) disassociation (also known as modular connection fatigue). To demonstrate that the proposed device is at least as safe and effective as the predicate device despite the compounding effects of these technological differences and previously outlined dimensional differences, fatigue (to assess resistance to fracture), wear, durability and modular connection fatigue performance tests were conducted (testing conclusions are described in more detail in *Section 18a Performance*

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Testing – Bench of this premarket notification submission). Stem loosening was not the focus of a performance test for the New Zimmer Total Elbow, because the variables (cementing technique, stem geometry, stem material and stem surface finish) associated with stem loosening are consistent from the predicate to the proposed device; and, therefore the proposed device (the New Zimmer Total Elbow) is expected to be as safe and effective as the predicate device (the Coonrad/Morrey Total Elbow) in terms of ability to resist stem loosening.

Could a limited flexion affect this? High stress at fixation interface at max range of flexion? 165°

As reflected in the dFMEA documentation associated with the proposed device, the Zimmer Nexel Total Elbow does not raise any new/different types of questions of safety or effectiveness.

The proposed and predicate devices have the exact same intended use. The proposed and predicate devices share similar indications for use; where, the only changes in wording of the indications for use are that the proposed device has indications for use that are intended to add specificity to the indications for use of the proposed device. This added specificity does not change the intended meaning of the indications for use of the proposed device as compared to those of the predicate.

Are there other predicates with ≤ 165° flexion?

Because the aforementioned differences between the proposed and predicate devices do not constitute a new intended use, affect safety or effectiveness or raise different questions of safety and effectiveness, these differences *do not* render the proposed device NSE (not substantially equivalent).

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Performance Specifications

Test	Test Results	
	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Fatigue Testing: Humeral Stem (Plasma Spray Region)	Five Zimmer Nexel Total Elbow humeral stems achieved (b)(4) load cycles at (b)(without fracture.	The predicate device humeral component was fatigue tested at various load levels, and the fatigue strength at (b)(4) cycles was determined to be (b)(
Fatigue Testing: Ulnar Stem (Mid-Stem Region)	Five Zimmer Nexel Total Elbow ulnar stems achieved (b)(4) load cycles in the mid-stem region at a load of (b) without fracture.	The predicate device ulnar component was fatigue tested at various load levels, and the fatigue strength at (b)(4) load cycles in the mid-stem region was determined to be (b)(
Fatigue Testing: Ulnar Stem (Plasma Spray Region)	Five Zimmer Nexel Total Elbow ulnar stems achieved (b)(4) load cycles in the plasma spray region at a load of (b)(without fracture.	The predicate device ulnar component was fatigue tested at various load levels, and the fatigue strength at (b)(4) load cycles in the plasma spray region was determined to be (b)
Wear Testing	The Zimmer Nexel Total Elbow mean gravimetric wear rate (b)(4) at (b)(4) load cycles) was 91% less than that of the predicate.	The predicate device mean gravimetric wear rate was (b) mg/Mc at (b)(4) load cycles.
Durability Testing	The Zimmer Nexel Total Elbow device achieved (b)(4) run-outs at an equivalent of (b) f weight-in-hand.	The run out load for the predicate device was found to be equivalent to (b)(4) weight-in-hand.
Modular Connection Fatigue Testing	The median fatigue strength of the non-articulating, mechanically locked, modular Zimmer Nexel Total Elbow implant components was no less than (b)(.	Not Applicable: The Zimmer Coonrad/Morrey Total Elbow does not have non-articulating, mechanically-locked, modular implant components comparable to those of the proposed device.

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Manual Orthopaedic Surgical Instruments

Recommendations for Care, Cleaning, Maintenance and Sterilization

zimmer

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1. Purpose

These instructions are recommended for the care, cleaning, maintenance and sterilization of reusable Zimmer orthopaedic manual surgical instruments. This document is intended to assist health care personnel in safe handling practices, effective reprocessing and maintenance of Zimmer reusable devices.

The manual is intended to assist the hospital and central supply management in developing procedures for safe and effective reprocessing of Zimmer instrument sets.

Hospital personnel, including those in receiving and central sterile supply departments (CSSD), as well as in the operating room (OR) may be directly involved in handling instruments purchased from Zimmer or on a loan basis as consignment instruments. Hospital directors and other management in each of these departments should be informed of these instructions and recommendations to ensure safe and effective reprocessing and to prevent damage or misuse of reusable devices.

2. Scope

This instruction manual provides information on the care, cleaning, disinfection, maintenance and sterilization of manual surgical instruments and is applicable to all reusable medical devices manufactured and/or distributed by Zimmer, Inc.

This information is also applicable to single-use medical devices manufactured by Zimmer that are supplied non-sterile but are intended to be used in a sterile state. These devices are single-use but can be reprocessed if not used (e.g. screws, plates, etc.). This also includes single-use devices packaged and sold sterile but removed from packaging and placed in kits.

Note: not used refers to those single-use components that have not been in contact with blood, bone, tissue or other body fluids. Any unused, single-use device that has been exposed to blood, bone, tissue or body fluids must not be reprocessed or resterilized and must be discarded.

Devices that cannot be reused may be labeled with the following symbol:

ISO 15223 3.2

Do not reuse

This information is not applicable to single-use devices that are sold sterile and cannot be resterilized (e.g. osteotome blades).

Devices that cannot be resterilized may be labeled with the following symbol:

ISO 15223 3.25

Do not resterilize

This instruction manual is not applicable to air driven or electrically powered equipment. However, it is applicable to functional attachments (e.g. reamers and drill bits) that are connected to powered equipment for use.

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3. Glossary

Chemical: a formulation of compounds intended for use in reprocessing.

Note: This includes detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners and sterilants.

Cleaning: the removal of contamination from an item to the extent necessary for further processing.

Contaminated: State of having been actually or potentially in contact with microorganisms.

Decontamination: the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or items is rendered safe for handling or disposal.

Disinfection: a process used to reduce the number of viable microorganisms on a product to a level previously specified as appropriate for its further handling or use.

Note: Cleaning and disinfection are often conducted in the same step.

Manual cleaning: cleaning without the use of an automated washer or washer/disinfector.

Processing/Reprocessing: activity including cleaning, disinfection and sterilization, necessary to prepare a new or used medical device for its intended use.

Sterile: free from all viable microorganisms.

Sterilization: a validated process used to render a device free from all forms of viable microorganisms.

Note: In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item may be expressed in terms of probability. While this probability may be reduced to a very low number, it can never be reduced to zero. This probability can only be assured for validated processes.

Washer/Disinfector: a machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical, and veterinary practice.

4. Acronyms

BI = biological indicator

CJD = Creutzfeldt-Jakob Disease

CSSD = Central Sterile Supply Department

OR = operating room

PPE = personal protective equipment

SAL = sterility assurance level

TSE = Transmissible Spongiform Encephalopathy

5. Symbols

ISO 15223 5.2

Do not reuse

ISO 15223 5.3

Consult instructions

ISO 15223 5.25

Do not resterilize

Caution or Instructions for Use

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6. Considerations

This instruction manual pertains to all Zimmer reusable surgical instruments and should be studied carefully. **This manual supercedes Zimmer and Centerpulse instrument manuals published prior to January 2006.**

The user/processor should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this manual.

New and used instruments **must** be thoroughly processed according to these instructions prior to use.

During musculoskeletal surgery, instruments become contaminated from blood, tissue, bone chips and marrow. The instruments may also become contaminated with body fluids containing hepatitis virus, HIV or other etiological agents and pathogens. All health care workers should become familiar with the necessary Universal Precautions of preventing injuries caused by sharp instruments when handling these devices during and after surgical procedures and during reprocessing.

It should be noted that saline and other irrigation fluids are often used in copious amounts during surgical procedures and will exert a corroding effect on instruments.

Orthopaedic surgery requires instruments which are heavy and have multiple components, articulating or rotating parts, removable handles, plastic replacement parts, and series of gauges or other measuring devices in graduated sizes. Devices are usually supplied in sets and subdivided into trays and cases in which the devices may be arranged by size or in the order needed for a specific surgical procedure.

Hospitals must assume responsibility for cleaning, disinfection, packaging and sterilization of all loaner instrument sets before returning them to Zimmer. However, the next user must also inspect the set upon receipt to verify that instruments have, in fact, been adequately cleaned and decontaminated before repeating reprocessing procedures to prepare the loaner set for subsequent reuse. Zimmer cannot guarantee that sterility was attained by the previous user and has been maintained during transit. Zimmer representatives often open and inspect instrument sets between users, which will, of course, compromise sterility and require complete reprocessing prior to subsequent use.

This manual includes instructions for all Zimmer reusable devices including legacy Centerpulse instruments marked with reprocessing category codes [a, a+, b, b+, c]. See Section 7 of this manual for further explanation of reprocessing codes. All Zimmer devices may be safely and efficiently reprocessed using the manual or combination manual/automated cleaning instructions outlined in this manual.

Core orthopaedic instrument sets must be complete and in good condition to be used correctly. Optional devices may be available on request from your Zimmer representative. To maintain instruments properly it is important to consider the following information and processing instructions:

- Warnings and precautions
- Instrument set completeness and functionality
- Reprocessing limitations and/or restrictions
- Preparation for reprocessing at the point of use
- Preparation for cleaning (including assembly/disassembly as necessary)
- Cleaning, disinfection and drying
- Maintenance, inspection, testing and lubrication
- Sterile packaging
- Sterilization
- Storage

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7. Processing Category Codes

The following codes are etched on some instruments and provide information useful in the selection of cleaning agents with appropriate pH. Zimmer recommends that all reusable devices (regardless of etching) be processed in accordance with the manual or combination manual/automated cleaning instructions contained in this instruction manual.

	Steel/metal instruments without cannulated bores/lumens or non-metal/polymer handles, or other components (e.g. retractors, drills, testing trays, rasps, scissors, clamps, exploring hooks, compression forceps, skin bridge elevators, guide wires, etc.). These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. These devices can be cleaned with rust-removal agents approved for surgical instruments in the presence of rust or corrosion.
	Steel/metal instruments with cannulated bores/lumens but without non-metal/polymer handles or other components (e.g. drills with elongated holes, belt tensioning pulleys, bone joint reamers, extractor cases). These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. These devices can be cleaned with rust-removal agents approved for surgical instruments in the presence of rust or corrosion. **Cannulations and hollow spaces must be cleaned manually.**
	Instruments made of polymers or metal instruments paired with polymer components (e.g. testing trays for flat profiles, chisels with non-metal handles, awls, dissectors, femur dilatators, pyramidal chisels/rasps). These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing.
	Instruments with cannulated bores, made of polymers or metal instruments paired with polymer components (e.g. tibial mallets, flex screwdrivers, tibial dilatators, etc.). These devices are tolerant of alkaline cleaning agents when followed by acidic neutralization and thorough rinsing. **Cannulations and hollow spaces must be cleaned manually.**
	Instruments made of titanium or aluminum alloys and/or having assembly/disassembly or other reprocessing aids (e.g. torque spanners, tibial aiming devices, pad cutters, instrument cases, trays and sterilization containers). These devices should be cleaned using the manual or combination manual/ automated cleaning procedures provided in this manual. **These devices should not be exposed to alkaline cleaning agents.**

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8. Processing Instructions

These processing instructions are intended to assist the hospital and central supply management in developing procedures to attain the above goals, both for hospital-owned and for loaned instrument sets. This information is based on Zimmer testing and experience, material science, as well as widely accepted recommendations of the following organizations:

- American National Standards Institute (ANSI)
- American Society for Testing and Materials (ASTM)
- Association for the Advancement of Medical Instrumentation (AAMI)
- Association of Operating Room Nurses (AORN)
- Centers for Disease Control (CDC)
- German Instrument Working Group (AKI) Arbeitskreis Instrumenten-Aufbereitung
- International Standards Organization (ISO)
- International Association of Healthcare Central Service Material Management (IAHCSMM)
- National Health Service (NHS)
- Robert Koch Institute (RKI)
- Swissmedic
- World Health Organization (WHO)

Note: These instructions describe the necessary processing steps that new and used instruments must undergo to attain sterility.

A. Warnings and Precautions

- **Universal Precautions should be observed** by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
- **Personal Protective Equipment (PPE) should be worn** when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- **Metal brushes or scouring pads must not be used** during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent formation of aerosols and splashing which may spread contaminants. Cleaning agents must be easily and completely rinsed from device surfaces to prevent accumulation of detergent residue.
- **Do not place heavy instruments on top of delicate devices.**
- **Do not allow contaminated devices to dry prior to reprocessing.** All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used instruments.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and **should not** be used. Instruments **must not** be placed or soaked in **Ringers Solution.**
- Mineral oil or silicone lubricants **should not** be used because they: 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.
- Only devices manufactured and/or distributed by Zimmer should be included in Zimmer instrument trays and cases. These validated reprocessing instructions are **not applicable** to Zimmer trays and cases that include devices that are not manufactured and/or distributed by Zimmer.
- Descaling agents that include morpholine should not be used in steam sterilizers. These agents leave residue which can damage polymer instruments over time.

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B. Receiving Inspection — Instrument set content and functionality verification

- Upon receipt in the hospital, instrument sets should be inspected for completeness. Inspect for thumb, wing, set, or other types of screws; screw-in or other detachable handles; and auxiliary exchangeable parts such as blades, right/left attachments or heads. Many organizing cases have shadow graphs, outlines, catalog numbers, and instrument names or sizes silk-screened or otherwise marked on the case or tray.
- Orthopaedic surgical procedures follow a precise order in which the instruments are used. Also, many instruments have dimensional features which govern bone resections, determine implant sizes, and measure intramedullary canal sizes, depth of drill holes, angles of tube/plate, acetabular cup placements, etc. Therefore, it is very important that all requested sizes of a specific instrument series are available (specific instruments are routinely omitted from instrument sets due to infrequent use unless requested by the user). Contact your Zimmer representative if requested instruments have been omitted but are required for surgery.
- Markings on instruments used for measuring anatomical dimensions must be legible. These may include gauge markings, angles, inner or outer diameters, length or depth calibrations, and right/left indications. Notify your Zimmer representative if scales and other markings are not legible.

C. Limitations and Restrictions

- Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning Zimmer reusable devices. Alkaline agents with pH of 12 or less may be used to cleanstainless steel and polymer instruments in countries where required by law or local ordinance; or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeldt-Jakob Disease (CJD) are a concern. **It is critical that alkaline cleaning agents are completely and thoroughly neutralized and rinsed from devices.**

Note: Drill bits, reamers, rasps and other cutting devices should be carefully inspected after processing with alkaline detergents to ensure that cutting edges are fit for use.

Note: It is important to select enzymatic solutions intended for breakdown of blood, body fluids and tissues. Some enzymatic solutions are specifically for breakdown of fecal matter or other organic contaminants and may not be suitable for use with orthopaedic instruments.

- Repeated processing, according to the instructions in this manual has minimal affect on Zimmer reusable manual instruments unless otherwise noted. End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended surgical use and not to reprocessing.
- Automated cleaning using a washer/disinfector alone **may not** be effective for orthopaedic instruments with lumens, cannulations, blind holes, mated surfaces and other complex features. A thorough, manual or combination manual/automated cleaning process is recommended.
- Where applicable, multi-component instruments should be disassembled for cleaning. Disassembly, where necessary, is generally self evident. Care must be taken to avoid losing small parts. If a part is lost, notify your Zimmer representative when the instrument set is returned.
- Instruments **must** be removed from metal or polymer trays for manual and/or automated cleaning procedures. **Do not** clean instruments while in polymer or metal trays. Instrument trays, cases and lids must be cleaned separately from instruments. Non-sterile, single-use plate and screw implants are an exception to this rule. Plates and screws may remain in the tray or caddy for reprocessing.
- Polymers used in Zimmer instrument sets can be sterilized using steam/moist heat. Polymer materials have a limited useful life. If polymer surfaces turn "chalky," show excessive surface damage (e.g. crazing or delamination), or if polymer devices show excessive distortion or are visibly warped, they should be replaced. Notify your Zimmer representative if polymer devices need to be replaced.
- Most currently available polymers will not withstand conditions in washer/sterilizers that operate at temperatures equal to or greater than 141°C/285°F, and use live-steam jets as cleaning features. Severe surface damage to polymer devices will occur under these conditions.

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- Soaking in disinfectants may be a necessary step to control certain viruses. However, these agents may discolor or corrode instruments (household bleach contains or forms chlorine and chloride in solution and has a corrosive effect similar to saline). Disinfectants containing glutaraldehyde, or other aldehydes, may denature protein based contaminants, causing them to harden and making them difficult to remove. Where possible, soaking in disinfectants should be avoided.
- Steam/moist heat is the recommended sterilization method for Zimmer instruments.
- Ethylene Oxide (EO), Gas Plasma Sterilization and dry heat sterilization methods are not recommended for sterilization of Zimmer reusable instruments.
- Instrument with removable polymer sleeves must be disassembled for sterilization (e.g. acetabular reamer shaft with sleeve, side cutters, etc.)
- During initial steam sterilization runs some formaldehyde from polyformaldehyde surfaces may vaporize and become noticeable. This should not cause concern. After a few sterilization cycles, the odor should be no longer evident.
- While ethylene oxide sterilization may prolong the service life of certain polymers (e.g. polysulfone), this method of sterilization is not recommended unless aeration times are provided in specific package inserts. Large polyformaldehyde items (DELRIN, CELCON) have been found to require excessive outgassing times (a minimum of five days at elevated temperatures in a mechanical aerator); therefore, **gas sterilization for polyformaldehyde products is contraindicated.**
- Titanium and titanium alloy devices are especially susceptible to discoloration from steam impurities and detergent residues which form multi-colored surface layers of oxide deposits. Upon repeated sterilization these oxide layers, while not harmful to the patient, may become so dark that they can obscure graduation marks, catalog and lot numbers, and other stamped or etched information. Acidic, anti-corrosion agents may be used to remove this discoloration. Avoid frequent use of these agents.
- Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments. One or more of the following processes may be used to purify water: ultra-filter (UF), reverse-osmosis (RO), deionized (DI), or equivalent.

D. Point of Use Preparation for Reprocessing

- Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.

Note: Soaking in proteolytic enzyme solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc.). These enzymatic solutions break down protein matter and prevent blood and protein based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.

- Instruments **should be** cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
- Used instruments **must be** transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

E. Preparation Before Cleaning

- Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.
- Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small screws and components. If a part is lost, notify your Zimmer representative when the instrument set is returned.
- Published instructions for use and surgical techniques and/or procedures may provide a supplemental source to illustrate assembly/disassembly instructions for specific Zimmer instruments.

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F. Preparation of Cleaning Agents

- **Neutral pH enzymatic and cleaning agents with low foaming** surfactants are preferred and recommended by Zimmer. Alkaline agents with pH of 12 or less may be used in countries where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and thorough rinsing.
- **All cleaning agents should be prepared at the use-dilution** and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.
- **Dry powdered cleaning agents should be completely** dissolved prior to use to avoid staining or corrosion of instruments.
- **Fresh cleaning solutions should be prepared when existing** solutions become grossly contaminated (bloody and/or turbid).

Table 1. Cleaning/Disinfection Options

Method	Description	Section
Manual	Enzymatic soak and scrub followed by sonication	G
Combination Manual/Automated	Enzymatic soak and scrub followed by automated washer/ disinfector cycle	H
Automated (Washer/Disinfector)	Washer/disinfector cycle - **not recommended for use without manual precleaning**	I

G. Manual Cleaning/Disinfection Instructions

1. Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
2. Remove the device from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
3. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50kHz.
4. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
5. Repeat the sonication and rinse steps above.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Note: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

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H. Combination Manual/Automated Cleaning and Disinfection Instructions

1. Completely submerge the instruments in enzyme solution and allow to soak for 10 minutes. Use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush (i.e. pipe cleaner).

Note: Use of a sonicator at 45-50kHz will aid in thorough cleaning of devices.

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

2. Remove devices from the enzyme solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.

3. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfection.

Table 2. Typical Automated Washer/Disinfector Cycle for Surgical Instruments

Step	Description
1	2 minute prewash with cold tap water
2	20 second enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 second cold tap water rinse (X2)
5	2 minutes detergent wash with hot tap water (64-66°C/146-150°F)
6	15 second hot tap water rinse
7	2 minute thermal rinse (80-93°C/176-200°F)
8	10 second purified water rinse with optional lubricant (64-66°C/146-150°F)
9	7 to 30 minute hot air dry (116°C/240°F)
Note: The washer/disinfector manufacturer's instructions should be strictly adhered to.	

I. Automated Cleaning/ Disinfection Instructions

1. Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. Orthopaedic instruments should be cleaned following the manual or combination manual/automated cleaning procedure outlined in this manual except where specifically indicated.

2. An automated washer/disinfector may be used as follow-up to the manual cleaning procedure above but is not required.

3. Simple instruments without multiple components, lumens/cannulations, blind holes, mated surfaces, connectors and internal mechanisms or other complex features may be successfully cleaned and disinfected using a typical washer/disinfector cycle for surgical instruments as outlined in Table 2 of this manual. Devices should be thoroughly inspected prior to sterilization to ensure effective cleaning.

J. Inspection, Maintenance, Testing and Lubrication

1. Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process.

2. Visually inspect for completeness, damage and/or excessive wear.

Note: If damage or wear is noted that may compromise the function of the instrument, contact your Zimmer representative for a replacement.

3. Check the action of moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.

4. Hinged, rotating, or articulating instruments should be lubricated with a water soluble product (e.g. Instrument Milk or equivalent lubricant) intended for surgical instruments that must be sterilized. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. To remain effective, the expiration date specified by the manufacturer should be adhered to for both stock and use-dilution concentrations.

Note: Mineral oil or silicone lubricants should not be used because they 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

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Note: These lubrication instructions are not applicable to air-powered or electrical instruments. These devices have different requirements and should be lubricated according to the manufacturer's instructions.

5. Check instruments with long slender features (particularly rotating instruments) for distortion.
6. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.

K. Sterile Packaging

Packaging individual instruments

- Commercially available, medical grade steam sterilization pouches (e.g. paper, Tyvek™ or equivalent) of the appropriate sizes may be used to double package single instruments. Ensure that the inner pouch is large enough to contain the instrument without stressing the seals or tearing the packaging but small enough to be placed in a secondary pouch without compromising the integrity of the total package.
- Standard medical grade, steam sterilization wrap may be used to package individual instruments. The package should be prepared using the AAMI double wrap or equivalent method.

Note: If sterilization wraps are used they must be free of detergent residues. Reusable wraps are not recommended.

Packaging instrument sets in rigid trays and cases with lids

Safety Precaution: The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs. When placed in a sterilization container with gasketed lid the total package should not exceed 16kg/35lbs.

- Trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.
- Trays and cases with lids may also be placed in an approved sterilization container with a gasketed lid for sterilization.

Note: Follow the sterilization container manufacturer's instructions for inserting and replacing sterilization filters in sterilization containers.

Instrument trays and cases with defined, preconfigured layouts

- Areas designated for specific devices shall contain only devices specifically intended for these areas.
- Optional Zimmer instruments should not be added to a preconfigured instrument tray or case unless a dedicated universal space or compartment has been included in the design and the guidelines described below for trays and cases without defined layouts or universal spaces can be applied.
- Only devices manufactured and/or distributed by Zimmer should be included in Zimmer instrument trays. These validated reprocessing instructions are **not applicable** to Zimmer trays that include devices that are not manufactured and/or distributed by Zimmer.

Universal instrument trays and cases without defined, preconfigured layouts or containing undefined universal spaces or compartments should only be used under the following conditions

- The total weight of a wrapped instrument tray or case should not exceed 11.4kg/25lbs. When placed in a sterilization container with gasketed lid the total sterilization package should not exceed 16kg/35lbs.
- Any device capable of disassembly must be disassembled prior to placement in the case.
- All devices must be arranged to ensure steam penetration to all instrument surfaces. Instruments should not be stacked or placed in close contact.
- The user must ensure that the instrument case is not tipped or the contents shifted once the devices are arranged in the case. Silicon mats may be used to keep devices in place.
- Only devices manufactured and/or distributed by Zimmer should be included in Zimmer instrument trays. Zimmer validated reprocessing instructions are **not applicable** to Zimmer trays that include devices that are not manufactured and/or distributed by Zimmer.

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L. Sterilization Instructions

- See Table 3 for recommended minimum sterilization parameters that have been validated by Zimmer to provide a 10^{-6} sterility assurance level (SAL).
- The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.
- **Moist heat/steam sterilization is the preferred and recommended method for Zimmer orthopaedic instrument sets.**
- Sterilizer manufacturer recommendations should **always** be followed. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.
- Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contract with all surfaces.
- Ethylene oxide or gas plasma sterilization methods **should not** be used unless package inserts for the applicable product specifically provide instructions for sterilization using these methods.
- Gravity displacement sterilization cycles are **not recommended** because cycle times are too long to be practical.

Table 3. Recommended Steam Sterilization Parameters

Cycle Type	Minimum Temperature	[6] Pressure	[7] Minimum Exposure Time		[11] Minimum Dry Time
			[8,9] Wrapped	[10] Unwrapped	
[4,5] UK Prevacuum/ Pulsating Vacuum	134°C 273°F	3bar 28.5psi	3 min	3 min	30 minutes
[4,5] Prevacuum/ Pulsating Vacuum	132°C 270°F	1.86bar 27psi	4 min	4 min	
[1,4] Prevacuum/ Pulsating Vacuum	134°C 273°F	3bar 28.5psi	18 min	18 min	
[3] Prevacuum/ Pulsating Vacuum	132°C 270°F	1.86bar 27psi	8 min	8 min	
[12] Gravity/Gravity Displacement	Not recommended due to excessively long sterilization cycles which are not practical.				

1 Minimum validated steam sterilization time required to achieve a 10^{-6} sterility assurance level (SAL).
2 Minimum validated steam sterilization temperature required to achieve a 10^{-6} sterility assurance level (SAL).
3 Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table.
4 Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination.
5 For Universal Instrument Cases without defined load configurations.
6 Sea level
7 AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable.
8 Medical grade steam sterilization compatible wrap equivalent to four thicknesses of 140-thread-count muslin.
9 Rigid sterilization container that complies with ANSI/AAMI ST46.
10 Flash (unwrapped) sterilization by exposure at 132°C /270°F should only be used as an emergency procedure. Instruments must be cleaned and disassembled.
11 Drying times vary according to load size and should be increased for larger loads.
12 Gravity steam sterilization cycle parameters are available on request from Customer Service.

Note: The Sterilizer Manufacturer's instructions for operation and load configuration should be followed explicitly.

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M. Storage Instructions

- Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
- Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

Note: Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be repackaged and sterilized.

Note: If there is any evidence that the lid seal or filters on a sterilization container have been opened or compromised, the sterile filters must be replaced and the instrument set resterilized.

9. Hospital Responsibilities for Zimmer Loaner Sets

- Orthopaedic surgical instruments generally have a long service life; however, mishandling or inadequate protection can quickly diminish their life expectancy. Instruments which no longer perform properly because of long use, mishandling, or improper care should be returned to Zimmer to be discarded. Notify your Zimmer representative of any instrument problems.
- Loaner sets should undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilization before being returned to Zimmer. Documentation of decontamination should be provided with instruments being returned to Zimmer.
- Missing or damaged instruments from loaner sets should be brought to the attention of the operating room supervisor, to the director of the central supply department, and to your Zimmer representative to ensure that the next hospital will receive a complete set of instruments in working condition.
- The instructions provided in this manual have been validated by Zimmer in the laboratory and are capable of preparing orthopaedic devices for use. It is the responsibility of the Hospital to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

10. Customer Service Information

Mailing Address	Telephone
Zimmer, Inc. 1800 West Center Street Warsaw, Indiana 46580 USA	Inside USA: 1-800-348-2759 Outside USA: local International access code +1-574-367-6131
Zimmer GmbH Sulzer-Allee 8 CH-8404 Winterthur, Switzerland	+41 (0)52 262 60 70
This Zimmer reprocessing manual and the associated Quick Reference Guide can be found at www.zimmer.com under the "Medical Professional" heading.	

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11. References

1. AAMI TIR12, *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*
2. AAMI TIR13, *Principles of industrial moist heat sterilization*
3. AAMI TIR30, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*
4. ANSI/AAMI ST33, *Guidelines for the selection and use of reusable rigid container systems for ethylene oxide sterilization and steam sterilization in health care facilities*
5. ANSI/AAMI ST35, *Safe handling and biological decontamination of reusable medical devices in healthcare facilities and in nonclinical settings*
6. ANSI/AAMI ST37, *Flash sterilization – Steam sterilization of patient care items for immediate use*
7. ANSI/AAMI ST46, *Steam sterilization and sterility assurance in health care facilities*
8. ANSI/AAMI ST67, *Sterilization of health care products – Requirements for products labeled "Sterile"*
9. ANSI/AAMI ST81, *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*
10. ANSI/AAMI/ISO 15223 and Amendments 1 and 2, *Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied*
11. AORN, *Standards, Recommended Practices and Guidelines*
12. ASTM F 565, *Standard Practice for Care and Handling of Orthopedic Implants and Instruments*
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17. Robert Koch Institute (RKI), *Hospital Supplies and Instrument Sterilization in Light of CJD Patients and Suspected CJD Cases*, Federal Health Gazette, 7/1998
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19. UK Department of Health, Health Technical Memorandum (HTM) 2030, *Washer-Disinfectors –Validation and Verification*
20. World Health Organization (WHO), WHO/CDS/CSR/APH 200.3, *WHO Infection Control Guidelines for TSE*

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Appendix 1. Cleaning/Disinfection Processes

Chart 1. Manual Cleaning/Disinfection Procedure

Step 1	Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Scrub using a soft-bristled, nylon brush until all visible soil has been removed.
Step 2	Remove the device from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
Step 3	Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50kHz.
Step 4	Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
Step 5	Repeat the sonication and rinse steps above.
Step 6	Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Chart 2. Combination Manual/Automated Cleaning/ Disinfection Procedure

Step 1	Completely submerge the instruments in enzyme solution and allow to soak for 10 minutes. Use a soft, nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush.
Step 2	Remove devices from the enzyme solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
Step 3	Place instruments in a suitable washer/disinfector basket and process through a standard washer/disinfector instrument cycle.

Chart 3. Typical Automated Washer/Disinfector Cycle for Cleaning/ Disinfection of Surgical Instruments

Step 1	Pre Wash; Cold Softened Tap Water; 2 minutes
Step 2	Enzyme Spray, Hot Softened Tap Water; 20 seconds
Step 3	Enzyme Soak; 1 minute
Step 4	Rinse (X2); Cold Softened Tap Water; 15 seconds
Step 5	Detergent Wash; Hot Softened Tap Water; (64-66°C/146-150°F); 2 minutes
Step 6	Rinse (X2); Hot Softened Tap Water; 15 seconds
Step 7	Thermal Rinse; Hot Softened Tap Water; (80-93°C/176-200°F); 2 minutes
Step 8	Purified Water Rinse; (64-66°C/146-150°F); 10 seconds
Step 9	Hot Air Dry; (116°C/240°F); 7 to 30 minutes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Manual Orthopaedic Surgical Instruments:
Recommendations for Care, Cleaning, Maintenance and Sterilization

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Allen, Peter

From: Hanley, Casey
Sent: Friday, December 28, 2012 3:49 PM
To: JOANNA.SURMA@ZIMMER.COM
Cc: Allen, Peter
Subject: *K123862 - Refuse to Accept Notification*
Attachments: rtax_K123862.pdf

Dear Ms. Surma,

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K123862) Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness.

Please refer to the attached checklist and e-mail your response referencing the 510(k) number K123862 by January 21, 2013. Your response should address all of the elements identified as missing or inconsistent in the attached checklist. Failure to provide the requested information by January 21, 2013 may result in placing the file on hold.

Upon receipt of the requested information, FDA may have additional requests for information.

Please be advised that once our RTA policy is implemented, if your 510(k) submission does not meet the criteria established for administrative completeness, your file will not be accepted and we will not begin our substantive review until you submit the missing elements and your submission is accepted. Refer to the draft guidance document for information.

Should you have questions about this email, you may either contact me or Peter Allen, the lead reviewer assigned to your 510(k) submission.

Sincerely,
Casey

Casey L. Hanley, Ph.D.
U.S. Food and Drug Administration
CDRH/ODE/DOD/JFOB
10903 New Hampshire Ave
WO66 Room 1567
Silver Spring, MD 20993
Tel: (301)796 6948
casey.hanley@fda.hhs.gov

This e mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential and it should not be disseminated distributed or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination distribution or copying is strictly prohibited If you think you have received this e mail message in error please e-mail the sender immediately.

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contains Nonbinding Recommendations
Draft - Not for Implementation

Acceptance Checklist
for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: K123862 **Date Received:** December 14, 2012

Lead Reviewer Name: Casey Hanley **Branch:** JFOB **Division:** DOD **Office:** ODE

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments:		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments:		
3. Is a 510(k) the appropriate regulatory submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	

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Comments:		
4. Is there a pending PMA for the same device with the same indications for use? If there is a pending PMA for the same device, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments:		
5. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.		X

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3 is no, the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 4 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 5 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation

	Yes	No
a. Submission contains Table of Contents	X	
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).*	X	
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	X	
Comments:		

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				Yes	N/A	No
Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.					
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc,)		X		☐
		Comments:				
	2.	510(k) cover letter that identifies:		X		☐
		a.	Device trade name or proprietary name	X		☐
		b.	Device common name	X		☐
		c.	Device class and panel	X		☐
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		X		☐
		Comments:				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*		X		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	☐	☐	X
		b.	Statement contains all elements per 21 CFR 807.93	☐	☐	☐
		Comments: **The 510(k) summary is missing a complete Device Description, (lacking**				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
		explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties) and is missing a comparison to predicate devices.			
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format*	X		☐
		Comments:			
	6.	Submission contains Class III Summary and Certification *See recommended content* *Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital signature.* *"N/A" only if submission is not a Class III 510(k).*	☐	X	☐
		Comments:			
	7.	If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed *There should be a completed form for each referenced national or international standard.* *"N/A" only if submission does not reference any standards.*	X	☐	☐
		Comments:			
	8.	Does submission contain clinical data? *Select "N/A" for this item and 8.a. and 8.b. if the submission does not contain clinical data. If submission does contain clinical data, parts a. and b. must be answered "yes" for the 510(k) to be complete.*	☐	X	

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		a.	Submission includes Financial Certification/Disclosure Statement	☐	X	☐
		b.	Submission includes Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B))	☐	X	☐
		Comments:				
	9.	If this is a bundled submission, the submission has been appropriately bundled [i.e., the correct user fee(s) have been paid for the devices/indications (section 738 of the FD&C Act)] *See* Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission. *"N/A" if not a bundled submission*		☐	X	☐
		Comments:				
	10.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions.		X		☐
		a.	If there were prior submissions: within current submission, the sponsor has identified where in the current submission any issues related to substantial equivalence outlined in prior communications are addressed.	☐	X	☐
		Comments:				
B.	**Device Description**					
	11.	If there is a device-specific guidance document or special controls applicable to this submission, documentation has been provided to		☐	X	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**No**
		establish that the submitter has followed the recommendations in the applicable device-specific guidance document or special controls regarding the device description or otherwise met the applicable statutory or regulatory criteria through an alternative approach. *Select "No" if the submission does not include a rationale for any omitted information or any alternative approaches.* *Select "N/A" if there is no device-specific guidance document*						
		Comments:					
	12.	All descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:					
		a.	A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.		X		☐
		b.	A description of all conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.		X		☐
		c.	A list and description of each model for which clearance is requested. *Select "N/A" if there is only one model.*		X	☐	☐
		Comments:					
	13.	Where applicable, submission contains engineering drawing(s), schematics, illustrations and/or figures of the device that are clear and legible, and include dimensions			X	☐	☐
		a.	If engineering drawings, schematics, illustrations and/or figures are provided, one is provided for each model to be marketed		X	☐	☐
		Comments:					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	14.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*			☐	
		a.	A description (as detailed in item 12.a. and b. and 13 above) is provided for each component or accessory.	X		☐
		b.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) do not have a prior 510(k) clearance.*	☐	X	☐
		Comments:				
C.	**Substantial Equivalence Discussion**					
	15.	Submitter has identified a predicate(s) device		X		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided	X		☐
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing	X		☐
		Comments:				
	16.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	X		☐
		b.	Technology, including features, materials, and principles of operation	X		☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
		Comments:			
	17.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that due to potential differences in manufacturing that may not be known to the submitter, no identified differences does not necessarily mean that no performance testing is needed.*	☐	☐	☒
		Comments: **The sponsor provides a tabulated comparison of the subject and predicate devices. From this tabulated list, it is clear there are differences between the subject and predicate devices with respect to indications for use and design features. The sponsor does not provide an analysis/discussion of why these differences do not render the device NSE.**			
D.	**Proposed Labeling (see also 21 CFR part 801)**				
	18.	Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual), and advertisements that describe the device, its intended use, and the directions for use	X		
		a. Indications for use stated in labeling (21 CFR 801.61) and identical to IFU form and 510(k) Summary (if applicable)	X		☐
		b. Directions for use included (including relevant hazards, warnings, precautions, contraindications), including directions for layperson (see 21 CFR 801.5) unless submission states that device qualifies	X		☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			for exemption per 21 CFR 801 Subpart D.			
		Comments:				
	19.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*		X	☐	☐
		Comments:				
	20.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	X		☐
		b.	Labeling includes device common or usual name (21 CFR 801.61)	X		☐
		Comments:				
	21.	If there is a device-specific guidance, special controls, or regulation, the provided labeling establishes that the submitter has followed the recommendations in the applicable guidance document, special controls, or regulation, or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no device-specific guidance or regulation.*		X	☐	☐
		Comments:				
	22.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*		☐	X	☐
E.	**Performance Data – General**					
	Submission: (*one of the below must be checked*) X does					

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	☐ does not contain performance data. *If "does not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	Comments:					
	23.	Full test report is provided for each completed test to explain how the data generated from the test supports a finding of substantial equivalence. (A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, and conclusions.)		X		☐
		Comments:				
	24.	Submission includes document to establish that the submitter has followed the recommendations for performance data outlined in the applicable device-specific guidance document or special controls, or otherwise met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no device-specific guidance document.*		X	☐	☐
		Comments:				
	25.	If literature was used as performance data, submission includes reprints or a summary of each article, and a discussion as to how each article is applicable to support the substantial equivalence of the subject device to the predicate.		☐	X	☐
		Comments:				
	26.	If an animal study was conducted, *Select "N/A" if no animal study was conducted.*			X	
		a.	Submission includes a study protocol and final study report to explain how the data generated from the study supports a finding of substantial equivalence. (A final study report includes a	☐		☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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			contributing scientist report for each preclinical endpoint of evaluation within the protocol, such as performance/handling, in life, imaging, pathology, etc.)			
		b.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐		☐
		Comments:				
F.	**Sterilization**					
	Submission states that the device and/or accessories are: (*one of the below must be checked*) X sterile X non-sterile but sterilized by the end user ☐ non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist.* *If information regarding the sterility status of the device is not provided, select "No."*					☐
	Comments:					
	27.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	X	☐	☐
		b.	Identification of device, and/or accessories, and/or components	☐	☐	X

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Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

				Yes	N/A	No
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.					
			that are end user sterilized			
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☐	☐	☒
	Comments: **The sponsor has identified a number of patient contacting instruments; however, the sponsor has not discussed whether they are provided sterile or non-sterile and whether they are able to be cleaned and re-sterilized. Therefore, please provide 1) a discussion as to which components are end user sterilized and 2) instructions for cleaning and re-sterilization for these components.**					
	28.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*			☐	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	X		☐
		b.	A description of method to validate the sterilization cycle (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided	X		☐
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	☐	☐	☒
		d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package)	X		☐
		e.	Sterility Assurance Level (SAL) stated	X		☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

				Yes	N/A	No
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.					
		f.	If device is blood-contacting, a permanent implant, or contacts cerebrospinal fluid, or device is labeled "non-pyrogenic," submission contains a description of the endotoxin method used to make a determination (e.g., LAL), endotoxin release specification (e.g., 20 EU/device), and a rationale for the specification. *Select "N/A" if device is not blood-contacting, not a permanent implant, does not contact cerebrospinal fluid, and is not labeled "non-pyrogenic." Select "N/A" if a rationale for omission is provided.*	☐	☐	☒
		Comments: **(c) The sponsor has provided a promissory note for EO residuals. Please provide EO residuals remaining on the device following sterilization validation.** **(f) The sponsor does not provide a rationale for omission of Pyrogen Testing.**				
	29.	All sterility information provided as recommended in the following guidance documents or special controls, or information provided indicating the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach: *Either "a" or "b" must be answered "Yes" to be considered complete.*				
		a.	Device-specific guidance document or special controls *Select "N/A" if no device-specific guidance document.*	☐	X	☐
		b.	Cross-cutting guidance document (for more information see "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile") *Select "N/A" if device-specific guidance followed instead.*	X	☐	☐
		Comments:				
G.	**Shelf Life**					
	30.	If the device is provided sterile or the device is provided non-sterile and storage conditions (i.e., aging) could impact device safety or			☐	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		effectiveness, address the following: *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*				
		a.	Proposed shelf life/expiry date stated	X		☐
		b.	Submission includes description of shelf life validation method(s) used to ensure device performance and sterility, as applicable, remain substantially equivalent to that of the predicate device throughout the stated shelf life.	X		☐
		Comments:				
H.	**Biocompatibility**					
	Submission states that there: (*one of the below must be checked*) X are ☐ are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."*					☐
	Comments:					
	31.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present		X		☐
		Comments:				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

			Yes	N/A	No
		• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			
	32.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	☐		☒
		Comments: **Sponsor does not state the contact classification for the instruments.**			
	33.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X		☐
I.	**Software**				
	Submission states that the device: (*one of the below must be checked*) ☐ does X does not contain software. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*				☐
	Comments:				
	34.	All appropriate categories of software verification and validation documentation provided based on stated level of concern, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided	☐		☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
		documentation that it has otherwise met the applicable statutory or regulatory criteria through an alternative approach.			
		Comments:			
J.	**EMC and Electrical Safety**				
	Submission states that the device: (*one of the below must be checked*) ☐ does X does not require EMC and Electrical Safety evaluation. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*				☐
	Comments:				
	35.	Submission includes evaluation of electrical safety per IEC 60601-1 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements.	☐		☐
		Comments:			
	36.	Submission includes evaluation of electromagnetic compatibility per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard	☐		☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements.				
		Comments:				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**					
	Submission indicates that device: (*one of the below must be checked*) ☐ is X is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	Comments:					
	37.	Submission includes the following analytical studies, including associated protocols and line data:				
		a.	Precision/reproducibility (at least 3 sites generally necessary)	☐	☐	☐
		b.	Accuracy (includes linearity, assay cut-off, method comparison or comparison to clinical outcome, matrix comparison, reference range, and stability protocol and acceptance criteria)	☐	☐	☐
		c.	Sensitivity (detection limits (LoB, LoD, and LoQ))	☐	☐	☐
		d.	Analytical specificity	☐	☐	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
		Comments:			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Contains Nonbinding Recommendations
Draft - Not for Implementation

Decision: Accept ___ Refuse to Accept X

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Casey Hanley 2012.12.27 09:41:57 -05'00'
Branch Chief Sign-Off	Anton E. Dmitriev 2012.12.27 14:45:32 -05'00'
Division Sign-Off	Mark N. Melkerson 2012.12.27 15:30:01 -05'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 14, 2012

ZIMMER, INC.
1800 WEST CENTER STREET
WARSAW, INDIANA 46580
ATTN: JOANNA L. SURMA

510k Number: K123862

Received: 12/14/2012

Product: ZIMMER NEXEL TOTAL ELBOW

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Pugh, Dominique *

From: Microsoft Outlook
To: Joanna.Surma@Zimmer.com
Sent: Friday, December 14, 2012 4:35 PM
Subject: Relayed: K123862 ACK LETTER & ECOPY ATTACHMENT

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

Joanna.Surma@Zimmer.com (Joanna.Surma@Zimmer.com)

Subject: K123862 ACK LETTER & ECOPY ATTACHMENT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

EXPLANATION FOR ECOPY ATTACHMENT

You provided an eCopy along with the required number of paper copies. Your eCopy did not pass our validation software. The specific reasons for this failure are identified in the attachment.

Because eCopies are currently voluntary and because you already provided the necessary number of paper copies, you do NOT need to provide a replacement eCopy to FDA.

Instead, FDA is providing you with this information so that you can understand the reasons why your eCopy failed in order to better assure that an eCopy that you submit for another submission will not have similar issues.

As additional resources:

- Refer to our eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf. The eCopy program is not implemented (i.e., eCopy remain voluntary) at this time; however, the technical specifications/standards in Attachment 1 of the guidance are already in place.

- We strongly encourage you to take advantage of our free new eSubmitter-eCopies tool at http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm317334.htm, which will help create an eCopy that passes the new technical specifications/standards.

Please keep in mind that once we implement the new eCopy program, most submissions types will go on eCopy hold until a valid eCopy is received.

If you have any questions about the eCopy program or the technical specifications/standards, please contact Ms. Samie Allen at samie.allen@fda.hhs.gov or at 301-796-6055.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Attachment

Attachment for Submission Number(s):

K123862

The list below identifies the reason(s) why your eCopy failed FDA's eCopy validation process.
All of these items need to be addressed or your eCopy will not pass the validation process.

1. **The following PDF file(s) exceeded maximum allowed file size limit of 50MB:**

   002_C-20121201_2012-12-13_001_02_FDA_Submission.pdf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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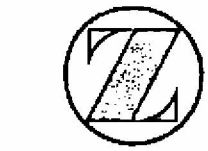
K129



P.O. Box 708
Warsaw, IN 46581-0708
(574) 267-6131

FDA CDRH DMC
DEC 14 2012
Received

13 December 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Sir or Madam:

Subject: Traditional 510(k) Premarket Notification – Zimmer Nexel Total Elbow – Prosthesis, Elbow, Constrained, Cemented – JDC – Class II – 21 CFR 888.3150

As required by Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, FDA Modernization Act of 1997 (FDAMA) and in accordance with Title 21 of the Code of Federal Regulations (CFR) Part 807, subpart E, the above noted premarket notification is hereby submitted to the Food and Drug Administration (FDA). As required by 21 CFR 807.90(c), this document is submitted in duplicate. A CD-ROM containing an eCopy that is an exact duplicate of the paper copy submission is also included for your convenience.

These devices have not been previously submitted to FDA for identical or different indications, are not currently being reviewed for different indications by the same or different branch within ODE, and have not been previously cleared by FDA for different indications.

If you require any additional information or have any questions, please contact me by telephone at (574) 371-1642, e-mail at Joanna.Surma@Zimmer.com or fax at (574) 372-4605.

Sincerely,

12 Dec 2012

Joanna L. Surma
Associate Project Manager, Regulatory Affairs

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Form Approved: OMB No. 0910-5111 Expiration Date: February 28, 2013. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ZIMMER INC
345 EAST MAIN STREET
WARSAW IN 46580
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****5416

2. CONTACT NAME
Joanna Surma
2.1 E-MAIL ADDRESS
Joanna.Surma@Zimmer.com
2.2 TELEPHONE NUMBER (include Area code)
574-371-1642
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)
30-Nov-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
12/13/2012	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Zimmer, Inc.			
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	(574) 371 - 1642		
Street Address	**FAX Number** *(including area code)*		
1800 West Center Street	(574) 372 - 4605		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Warsaw	Indiana	46580	USA
Contact Name			
Joanna L. Surma			
Contact Title	**Contact E-mail Address**		
Associate Project Manager, Regulatory Affairs	Joanna.Surma@Zimmer.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
Street Address	**FAX Number** *(including area code)*		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change.
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	JDC	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [X] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K001918	the Coonrad/Morrey Total Elbow	Zimmer
2	K053189	the Coonrad/Morrey Total Elbow	Zimmer
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Prosthesis, Elbow, Constrained, Cemented

	Trade or Proprietary or Model Name for This Device	Model Number
1	Zimmer Nexel Total Elbow	NA
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [X] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
JDC	21 CFR 888.3150	[ ] Class I [X] Class II
Classification Panel: Orthopedic		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

Indications for use include: (1) Elbow joint destruction which significantly compromises the activities of daily living. (2) Post-traumatic lesions or bone loss contributing to elbow instability, (3) Ancient sepsis that results in ankylosed joints, especially in cases of bilateral ankylosis, (4) Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain, (5) Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis, (6) Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus, (7) Revision arthroplasty. *CAUTION: This device is intended for cemented use only.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Zimmer, Inc		Establishment Registration Number: 1822565	
Division Name *(if applicable)*		Phone Number *(including area code)*: (574) 372-4964	
Street Address: 1800 West Center Street		FAX Number *(including area code)*: (574) 372-4605	
City: Warsaw	State / Province: Indiana	ZIP Code: 46580	Country: USA
Contact Name: Carol Vierling	Contact Title: Director, Corporate Regulatory Affairs	Contact E-mail Address: Carol.Vierling@Zimmer.com	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: (b)(4)		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: (b)(4)	
Street Address: (b)(4)		FAX Number *(including area code)*	
City: (b)(4)	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address: (b)(4)	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: (b)(4)		Establishment Registration Number	
Division Name *(if applicable)*: (b)(4)		Phone Number *(including area code)*	
Street Address: (b)(4)		FAX Number *(including area code)*	
City: (b)(4)	State / Province	ZIP Code	Country
Contact Name: (b)(4)	Contact Title	Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	14283	ISO	Implants for surgery – Fundamental principles		07/08/2004
	Standards No.	Standards Organization	Standards Title	Version	Date
2	14630	ISO	Non-active surgical implants -- General requirements		01/07/2008
	Standards No.	Standards Organization	Standards Title	Version	Date
3	F1980	ASTM	Standard Guidance for Accelerated Aging of Sterile Barrier Systems for Medical Devices		04/01/2007
	Standards No.	Standards Organization	Standards Title	Version	Date
4	ST81	AAMI	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices		12/02/2004
	Standards No.	Standards Organization	Standards Title	Version	Date
5	10993-1	ANSI AAMI ISO	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process		10/15/2009
	Standards No.	Standards Organization	Standards Title	Version	Date
6	10993-3	ANSI AAMI ISO	Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity		10/15/2003
	Standards No.	Standards Organization	Standards Title	Version	Date
7	10993-5	ANSI AAMI ISO	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity		06/01/2009

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	10993-6	ANSI AAMI ISO	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity		4/15/2007
	Standards No.	Standards Organization	Standards Title	Version	Date
2	10993-7	ANSI AAMI ISO	Biological Evaluation of Medical Devices – Part 7. Ethylene oxide sterilization residuals		10/15/2008
	Standards No.	Standards Organization	Standards Title	Version	Date
3	10993-10	ANSI AAMI ISO	Biological Evaluation of Medical Devices – Part 10. Tests for irritation and delayed-type hypersensitivity Amendment 1		8/01/2006
	Standards No.	Standards Organization	Standards Title	Version	Date
4	10993-11	ANSI AAMI ISO	Biological Evaluation of Medical Devices – Part 11. Tests for systemic toxicity		8/15/2006
	Standards No.	Standards Organization	Standards Title	Version	Date
5	11135-1	ANSI AAMI ISO	Sterilization of Health Care Products – Ethylene Oxide Part 1: Requirements for Development, Validation, and Routing Control of a Sterilization Process for Medical Devices		9/01/2007
	Standards No.	Standards Organization	Standards Title	Version	Date
6	11137-1	ANSI AAMI ISO	Sterilization of Health Care Products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices		8/01/2006
	Standards No.	Standards Organization	Standards Title	Version	Date
7	11137-2	ANSI AAMI ISO	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose		2/15/2009

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SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	F136	ASTM	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications		11/01/2008
2	F648	ASTM	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants		02/01/2007
3	F1537	ASTM	Specifications for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants		05/10/2000
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to

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K123862

K24

P.O. Box 708
Warsaw, IN 46581-0708
(574) 267-6131

ZIMMER®

13 December 2012

FDA CDRH DMC
DEC 14 2012
Received

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Sir or Madam:

Subject: Traditional 510(k) Premarket Notification – Zimmer Nexel Total Elbow – Prosthesis, Elbow, Constrained, Cemented – JDC – Class II – 21 CFR 888.3150

As required by Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, FDA Modernization Act of 1997 (FDAMA) and in accordance with Title 21 of the Code of Federal Regulations (CFR) Part 807, subpart E, the above noted premarket notification is hereby submitted to the Food and Drug Administration (FDA). As required by 21 CFR 807.90(c), this document is submitted in duplicate. A CD-ROM containing an eCopy that is an exact duplicate of the paper copy submission is also included for your convenience.

These devices have not been previously submitted to FDA for identical or different indications, are not currently being reviewed for different indications by the same or different branch within ODE, and have not been previously cleared by FDA for different indications.

If you require any additional information or have any questions, please contact me by telephone at (574) 371-1642, e-mail at Joanna.Surma@Zimmer.com or fax at (574) 372-4605.

Sincerely,

Joanna L Surma 13 Dec 2012

Joanna L. Surma
Associate Project Manager, Regulatory Affairs

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name:

Zimmer Nexel Total Elbow

Indications for Use:

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

CAUTION: This device is intended for cemented use only.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Joanna L. Surma Associate Project Manager, Regulatory Affairs Telephone: (574) 371-1642 Fax: (574) 372-4605
Date:	13 December 2012
Trade Name:	Zimmer Nexel Total Elbow
Common Name:	Total Elbow Prosthesis
Classification Name and Reference:	Prosthesis, Elbow, Constrained, Cemented 21 CFR § 888.3150
Product Code:	JDC
Predicate Device:	Coonrad/Morrey Total Elbow, manufactured by Zimmer, K001989, cleared 25 July 2000 Coonrad/Morrey Total Elbow, manufactured by Zimmer, K053189, cleared 9 December 2005
Device Description:	The Zimmer Nexel total Elbow is a total elbow prosthesis designed for use with bone cement. It is available in multiple sizes and in right and left configurations.

Intended Use:
Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

Caution: This device is intended for cemented use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Comparison to Predicate Device:

The Zimmer Nexel Total Elbow is substantially equivalent to the predicate device in terms of form and function. The Zimmer Nexel Total Elbow and the predicate device share similar intended uses and indications for use.

Performance Data:

Non-Clinical Performance Testing Conducted:

- Stem Fatigue Testing
- Wear Testing
- Durability Testing
- Modular Connection Fatigue Testing

Non-Clinical Performance Testing Conclusions:

Non-clinical testing demonstrated that the New Zimmer Total Elbow meets performance requirements as defined by Design Control activities and is substantially equivalent to the predicate device in terms of safety and efficacy.

In this case, clinical data and conclusions were not needed to demonstrate substantial equivalence.

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zimmer

Traditional 510(k)
Premarket Notification

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Associate Project Manager (title) of Zimmer, Inc. (company name), I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

13 Dec 2012
(Signature)

Joanna L. Surma
(Typed Name)

13 Dec 2012
(Date)

(Premarket Notification [510(k)] Number)

TRV

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Class III Summary and Certification

This device is class II; therefore, this section does not apply.

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Financial Certification or Disclosure Statement

This submission does not contain any clinical data; therefore, this section does not apply.

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Declarations of Conformity and Summary Reports

This device conforms to the following recognized standards; a Standards Data Report (FDA Form 3654) is included below for each standard.

- ISO 14283 *Implants for surgery – Fundamental principles*
- ISO 14630:2008 *Non-active Surgical Implants – General Requirements*
- AAMI ST81:2004/(R)2010 *Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices*
- ANSI/AAMI/ISO 10993-1:2009 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing* within a risk management process
- ANSI/AAMI/ISO 10993-3:2003 *Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- ANSI/AAMI/ISO 10993-5:2009 *Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity*
- ANSI/AAMI/ISO 10993-6:2007 *Biological Evaluation of Medical Devices – Part 6: Tests for local effects after implantation*
- ANSI/AAMI/ISO 10993-7:2008 *Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals*
- ANSI/AAMI/ISO 10993-10:2002/Amd.1:2006(E) *Biological Evaluation of Medical Devices – Part 10: Tests for irritation and delayed-type hypersensitivity Amendment 1*
- ANSI/AAMI/ISO 10993-11:2006 *Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity*
- ANSI/AAMI/ISO 11135-1:2007 *Sterilization of Health Care Products – Ethylene Oxide Part 1: Requirements for Development, Validation, and Routing Control of a Sterilization Process for Medical Devices*
- ANSI/AAMI/ISO 11137-1:2006 *Sterilization of Health Care Products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
- ANSI/AAMI/ISO 11137-2:2009 *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*
- ASTM F136-08 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*
- ASTM F648-07 *Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants*
- ASTM F1537-00 *Specifications for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants*
- ASTM F1980-07 *Standard Guidance for Accelerated Aging of Sterile Barrier Systems for Medical Devices*

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Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14283: 2004 Implants for Surgery – Fundamental Principles

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k)	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U S C 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described, deviations from the standard, requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
· ISO 14283: 2004 Implants for Surgery – Fundamental Principles

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
None. Conformance to all indicated sections.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14630: 2008 Non-active Surgical Implants – General Requirements

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] #11-208		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14630: 2008 Non-active Surgical Implants – General Requirements

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
None. Conformance to all indicated sections.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1980-07 Standard Guidance for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-229	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F1980-07 Standard Guidance for Accelerated Aging of Sterile Barrier Systems for Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
None. Conformance to all indicated sections.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI ST81:2004/(R)2010 Sterilization of medical devices— Information to be provided by the manufacturer for the proc...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-295	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☒
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?.. If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C 360d], http://www.fda gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http //www accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI ST81:2004/(R)2010 Sterilization of medical devices— Information to be provided by the manufacturer for the proc...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
None. Conformance to all indicated sections.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-1:2009 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Manage...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 10993-1:2009 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Manage...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
A biological evaluation was conducted per ISO 10993-1, which led to the selected ISO 10993 testing options such as 5.2.2 Cytotoxicity, 5.2.3 Sensitization, 5.2.5 Intracutaneous Reactivity, 5.2.6 Systemic Toxicity

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-3:2003/(R)2009 Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenic...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-117	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is. [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C 360d]. http://www fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default htm

[3] http://www.accessdata.fda gov/scripts/cdrh/cfdocs/cfStandards/search cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 10993-3:2003/(R)2009 Biological Evaluation of Medical Devices - Part 3: Tests for Genotoxicity, Carcinogenic...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Test options selected include: Bacterial Reverse Mutation, Mouse Lymphoma Assay, and Mouse Peripheral Blood Micronucleus Study

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Test options selected include a cytotoxicity study using the elution method

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-6:2007 Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects after Implantation

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-120	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance:		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 10993-6:2007 Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects after Implantation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Test options selected include muscle implantation studies in rabbits at 2 and 12 weeks

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 14-278		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d]. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2 & 4.3	4.2) Categorization of Medical Devices 4.3) Allowable Limits	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
The Vitamin E HXPE Bearings and the Zimaloy Axle-Pin are categorized as permanent contact devices (greater than 30 days of contact).

DESCRIPTION
The EO and ECH limits for permanent contact devices were utilized

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4	Determination of EO and ECH Residuals	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Exhaustive Extraction Method is utilized instead of simulated use method

DESCRIPTION
Provided all applicable limits are met & residues shown to be within limits for exhaustive extraction there is no need to test with simulated use

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All others	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
None. Conformance to all indicated sections.

JUSTIFICATION

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STANDARD TITLE [1]

ISO 10993-10:2002/Amd. 1:2006(E) Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] #2-152		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-10:2002/Amd. 1:2006(E) Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Test options selected include the guinea pig maximization test

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-11:2006 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C 360d], http://www fda gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default htm

[3] http //www.accessdata fda gov/scripts/cdrh/cfdocs/cfStandards/search cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device, and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http // www accessdata fda gov/scripts/cdrh/cfdocs/cfStandards/search cfm

[6] The online search for CDRH Guidance Documents can be found at http //www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 10993-11:2006 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Test options selected include 13 and 26 week systemic toxicity study in rats following subcutaneous implantation and systemic toxicity study in mice

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11135-1: 2007 Sterilization of Health Care Products – Ethylene Oxide Part 1: Requirements for Development...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-228	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d]. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 11135-1: 2007 Sterilization of Health Care Products – Ethylene Oxide Part 1: Requirements for Development...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-12	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
None. Conformance to all indicated sections

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11137-1: 2006 Sterilization of health care products – Radiation – Requirements for development, validation...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-297	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ANSI/AAMI/ISO 11137-1: 2006 Sterilization of health care products – Radiation – Requirements for development, validation...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

None. Conformance to all indicated sections.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 11137-2: 2009 Sterilization of health care products - Radiation - Establishing the sterilization dose

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-225	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is. [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d]. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI/ISO 11137-2: 2009 Sterilization of health care products - Radiation - Establishing the sterilization dose

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-6, 9-11	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
None. Conformance to all indicated sections.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7-8	Dose Setting using Bioburden/Fraction Positive Information...	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION

JUSTIFICATION
Methods described in sections 7 and 8 are not utilized; VDmax method is utilized as described in section 9.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]:

ASTM F136-08 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-164	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F136-08 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
None. Conformance to all indicated sections.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F648-07 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] #8-178		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

[1] The formatting convention for the title is [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described, deviations from the standard, requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F648-07 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
None. Conformance to all indicated sections.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1537-00 Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-182	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U S C 360d], http://www fda gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default htm

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[4] The summary report should include any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard The summary report includes information on all standards utilized during the development of the device.

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[6] The online search for CDRH Guidance Documents can be found at http //www fda gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
· ASTM F1537-00 Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	Various	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
None. Conformance to all indicated sections.

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Device Name

Zimmer Nexel Total Elbow

Reason for the Submission

Zimmer is seeking clearance to market the Zimmer Nexel Total Elbow, which has not previously been marketed.

Device Description

Overview

The Zimmer Nexel Total Elbow is designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a semi-constrained device assembly and consists of a *humeral component*, an *ulnar component*, a *humeral bearing-A*, 2 *ulnar bearings-B*, an *axle pin* and 2 *humeral screws*.

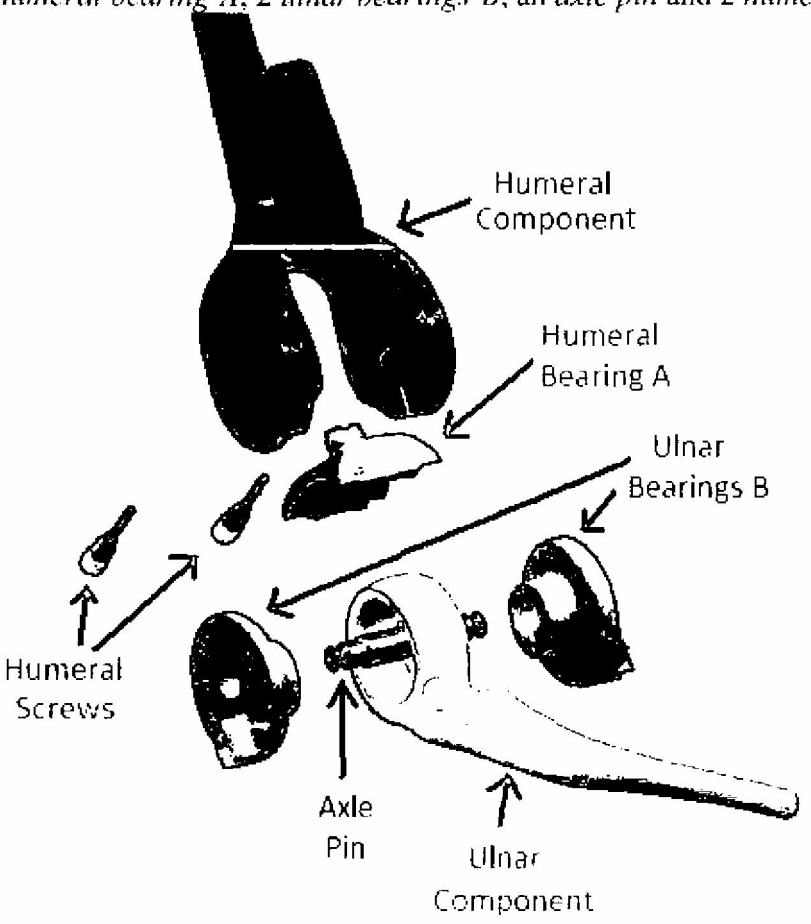

Image 10.1: The Zimmer Nexel Total Elbow, exploded view

A detailed description of the proposed device is presented in Section 11, Device Description.

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Indications for Use

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

CAUTION: This device is intended for cemented use only.

Submission Overview

The table below provides a comparison between the proposed and predicate devices. Additional information is presented in Section 12, Substantial Equivalence Discussion.

		Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Humeral Component	Stem with Triangular Cross-Section	X	X
	Straight Stem	X	X
	Anterior Flange	X	X
	Titanium Alloy	X	X
	Titanium Beads on Distal Region		X
	Titanium Plasma Spray on Distal Region	X	
Ulnar Component	Stem with Quadrangular Cross-Section	X	X
	Curved Stem	X	X
	Nitrogen Enriched Surface Hardening of Ulnar Eye	X	
	Titanium Alloy	X	X
	Titanium Plasma Spray on Proximal Region	X	X
Linkage	2-Part, Hollow Snap-Pin		X
	Solid Axle Pin	X	
	Screws	X	
Semi-Constrained		X	X
Terminal Sterilization		X	X
Titanium-on-Polyethylene Articulation		X	X

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Performance Testing

The following performance testing was conducted on the Zimmer Nexel Total Elbow. A detailed summary and copy of each test report are included in Section 18, Performance Testing – Bench.

Stem Fatigue Testing

The fatigue strength of the Zimmer Nexel Total Elbow humeral component distal stem at (b)(4) load cycles is (b)(, which is (b) stronger than that of the legally marketed Zimmer Coonrad/Morrey Total Elbow humeral component (b)(4) at a comparable point on the distal stem.

The fatigue strength of the Zimmer Nexel Total Elbow ulnar component stem in the mid-stem region at (b)(4) load cycles is at least (b)((the fatigue strength of the legally marketed Zimmer Coonrad/Morrey Total Elbow ulnar component at a comparable point on the stem).

The fatigue strength of the Zimmer Nexel Total Elbow ulnar component stem in the plasma spray (proximal stem) region at (b)(4) load cycles is at least (b)((the fatigue strength of the legally marketed Zimmer Coonrad/Morrey Total Elbow ulnar component at a comparable point on the stem).

These studies demonstrated that the Zimmer Nexel Total Elbow is at least as safe and effective as the predicate device (Zimmer Coonrad/Morrey Total Elbow) in terms of humeral and ulnar stem fatigue strength.

Wear Testing

The Zimmer Nexel Total Elbow mean gravimetric wear rate ((b)(4) at (b)(4) load cycles) was (b) less than that of the predicate.

This study demonstrated that the Zimmer Nexel Total Elbow met or exceeded all acceptance criteria and is at least as safe and effective as the predicate device in terms of wear performance.

Durability Testing

The Zimmer Nexel Total Elbow device achieved (b)(4) run-outs at the equivalent of (b)(4) weight-in-hand (b)(4) peak JRF and (b)(4) varus-valgus moment), a load level (b)(higher than the load level at which the predicate device ran out.

This study demonstrated that the Zimmer Nexel Total Elbow is at least as safe and effective as the predicate device in terms of durability.

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Modular Connection Fatigue Testing

The median fatigue strength of the non-articulating, mechanically locked, modular Zimmer Nexel Total Elbow implant components was no less than (b)(4)

This study demonstrated that the Zimmer Nexel Total Elbow is safe and effective in terms of non-articulating, mechanically locked, modular connection fatigue.

Support Research

The following internal (Zimmer) research and testing informed and/or support the aforementioned testing and can be found in their entirety at the end of Section 18, Performance Testing – Bench.

- Zimmer Research Memo ZRM_WA_0179_09, *Analysis of Retrieved Coonrad/Morrey Elbow Total Arthroplasty Components*
- Zimmer Research Memo ZRM_WA_0193_09, *Development of the Coonrad/Morrey Elbow Durability Test*
- Zimmer Research Report ZRR_WA_1988_09, *Literature Review Summary of Elbow Joint Mechanics and Total Elbow Arthroplasty Outcomes*
- Zimmer Research Report ZRR_WA_2252_10, *Evaluation of the AS/BF Taper Adaptor Component Using Electrochemical Test Methods*
- Zimmer Technical Memo 1222.00, *Fatigue Strength of Plasma Sprayed Ti-6AL-4V Alloy Material*
- Zimmer Research Memo ZRM_WA_0292_11, *Summary of Clinical Complications of the Coonrad/Morrey Elbow System*
- Zimmer Research Report ZRR_WA_2338_11, *Vitamin E Highly Crosslinked Polyethylene Shelf Life Study*
- Zimmer Research Report ZRR_WI_2441_11, *Finite Element Analysis of the Coonrad-Morrey Total Elbow System*
- Zimmer Research Report ZRR_WA_2476_11, *Biomechanics Rationale for the Loading of Total Elbow Prosthesis During In Vitro Simulations*
- Zimmer Research Report ZRR_WA_2481_11, *Determination of the Functional Torque Range of the New Zimmer Total Elbow Humeral Screw and Hex Driver*
- Zimmer Technical Memo 1217.00, *Coonrad/Morrey Elbow Ulnar Stem Fatigue Testing*
- Zimmer Technical Memo 1218.00, *Coonrad/Morrey Humeral Stem Fatigue Testing*
- Memo to DHF File Z07-014, *Rationale for Determination of Torque Specification and Torque Range Requirement for the Mechanical Fastening Used in Zimmer New Total Elbow Prosthesis*

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- Zimmer Research Report ZRR_WA_2646_12, *Pin-on-Flat Wear Comparison of the New Zimmer Total Elbow and the Coonrad-Morrey Articulation Couples*
- Zimmer Research Report ZRR_WA_2648_12, *Finite Element Analysis of Nexel Elbow Ulnar Implant Neck Region*
- Zimmer Research Report ZRR_WI_2441_11, *Finite Element Analysis of the Coonrad-Morrey Total Elbow System*

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Device Description

Overview

The Zimmer Nexel Total Elbow is an implant designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a semi-constrained device assembly and consists of the following components, which are described in more detail below:

- Humeral Component
- Ulnar Component
- Humeral Bearing-A
- 2 Ulnar Bearings-B
- Axle Pin
- 2 Humeral Screws

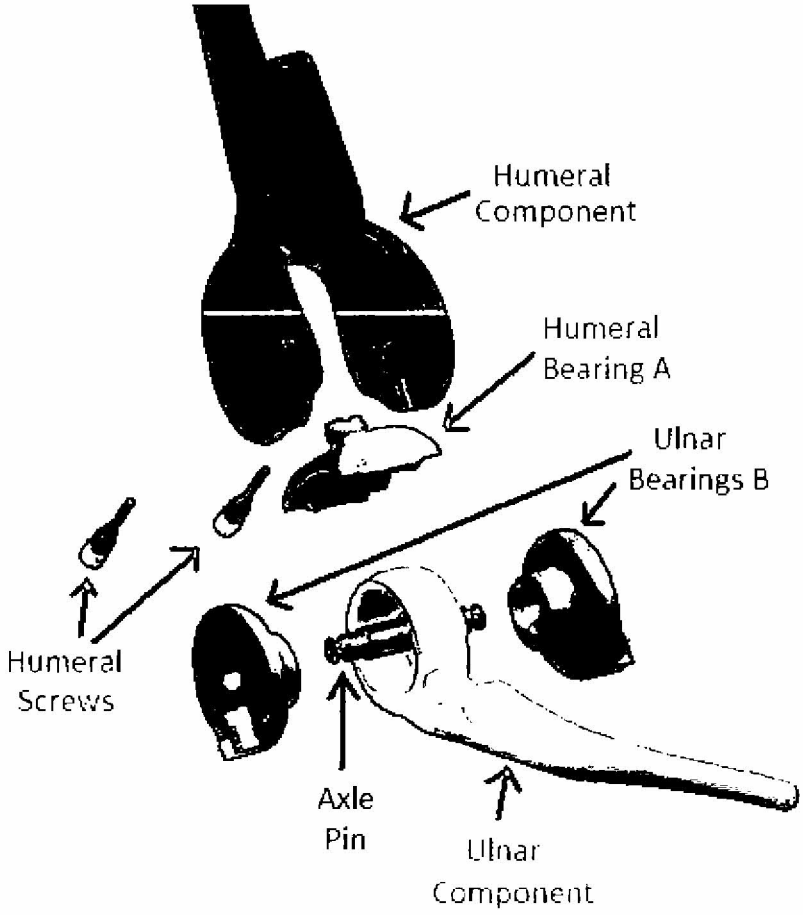

Image 11.1: The Zimmer Nexel Total Elbow, exploded view

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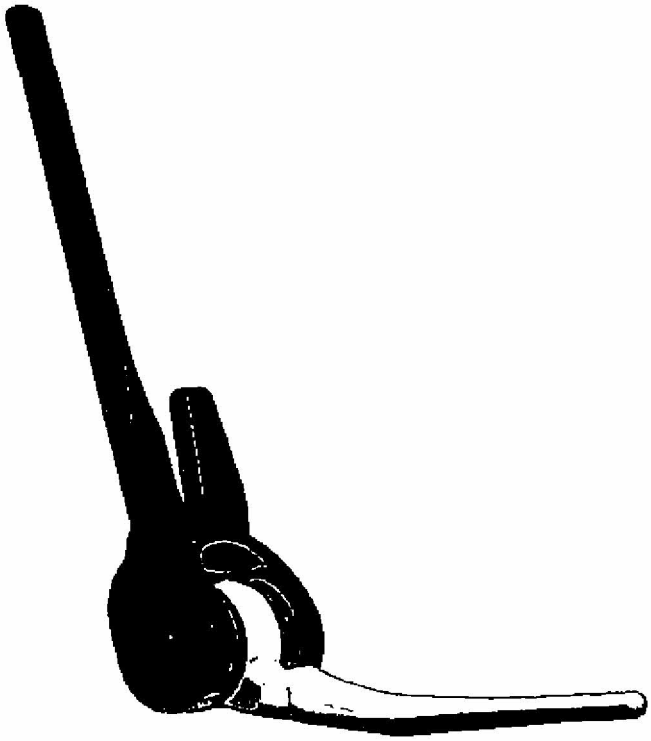

Image 11.2: The Zimmer Nexel Total Elbow, assembled

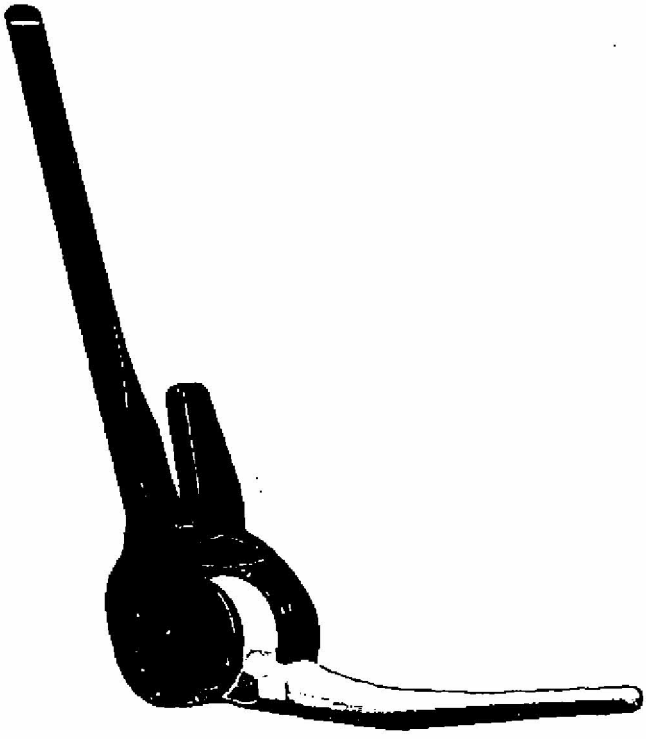

Image 11.3: The Zimmer Nexel Total Elbow, assembled with Humeral Component translucent

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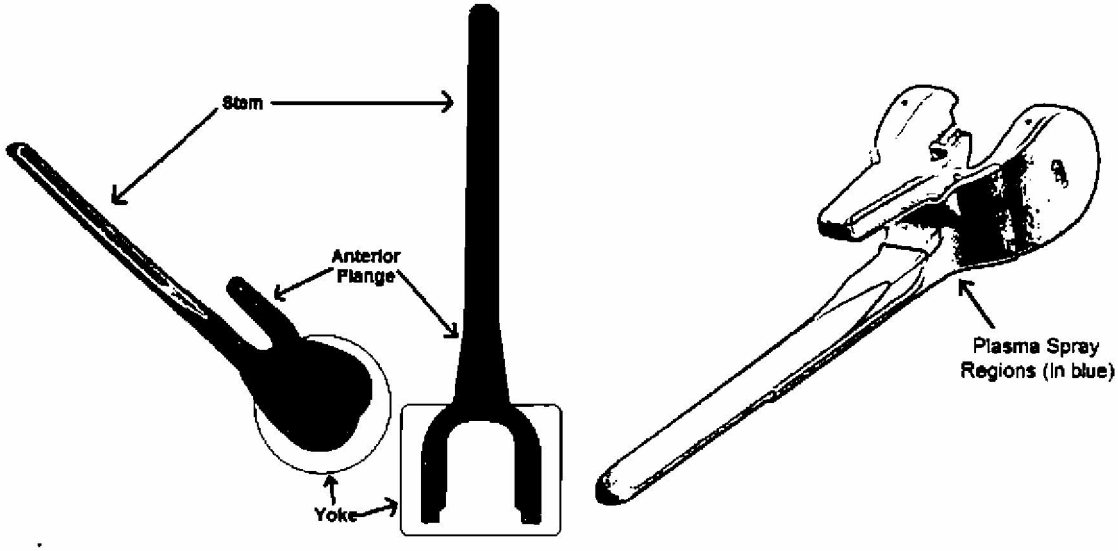
Humeral Component

The *humeral component* is made from wrought *Tivanium* alloy (Ti-6Al-4V) and has the following major design features: a *stem*, an *anterior flange*, a *yoke* and *plasma spray regions*.



Humeral Component, major design features

The *humeral stem* is intended to be implanted with bone cement into the patient's humeral medullary canal. It has a triangular cross-section, which is designed to prevent rotation of the *humeral component* within the patient's medullary canal; and, it is straight along its proximal-distal axis to conform to the straight shaft of the distal humeral medullary canal.

The *humeral anterior flange* is designed to accept a bone graft, which is wedged between the *anterior flange* and the exterior cortical bone of the humeral shaft. This *anterior flange* and bone graft combination are intended to improve both anti-rotational stability and posterior migration of the *humeral component*, thereby resisting stem loosening.

The *humeral yoke* has rounded corners (as opposed to angular) on its proximal surface in order to prevent stress risers (that are often associated with bone preparation cuts required for angled corners abutting bone). This rounded *yoke* design is intended to preserve the strength of (and avoid fracture of) the medial and lateral supracondylar columns. The *yoke* walls also house partially threaded holes with Spiralock® technology (tap manufactured by Stanley Black & Decker, Madison Heights, MI), which engage with the *humeral screws*.

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The *humeral component* has several regions covered in plasma spray, which is contained within the Plasma Sprayed Titanium-6Al-4V Alloy Coating Material Master File (FDA Ref: MAF-1909, Letter of Authorization can be found in Section 21). The *plasma spray regions* are designed to increase the coefficient of friction between the implant and the bone cement, thereby improving anti-rotational stability and aiding in resistance to movement of the implant with respect to the humerus.

In addition to the aforementioned major design features, the *humeral component* also includes the following features to accept the *axle-pin* and *bearings A and B*: v-grooves at the base of the keyways to accept the *axle-pin*, a hole to accept *humeral bearing-A* and two keyways to accept *ulnar bearings-B*.

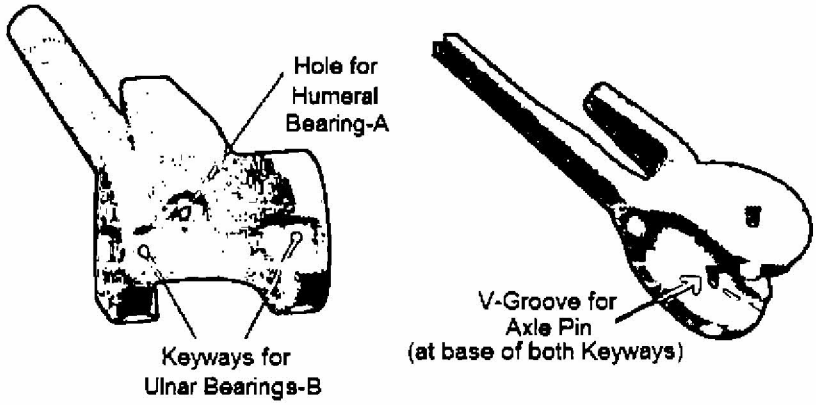

Image 11.5: Humeral Component, design features for mating to bearings and axle-pin

Ulnar Component

The *ulnar component* is made from wrought *Tivanium* alloy (Ti-6Al-4V) and has the following major design features: a *stem*, an *eye* and a *plasma spray region*.

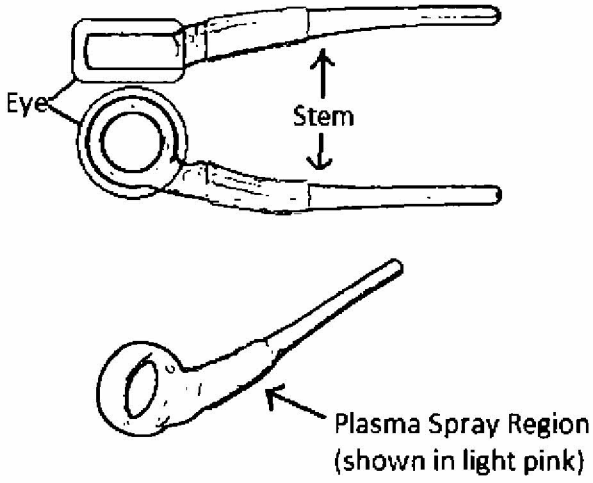

Image 11.6: Ulnar Component, major design features

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The *ulnar stem* is intended to be implanted with bone cement into the patient's ulnar medullary canal. It has a quadrangular cross-section, which is designed to prevent rotation of the *ulnar component* within the patient's medullary canal; and, it is curved along its proximal-distal axis to conform to the curved shaft of the proximal ulnar medullary canal.

The *ulnar eye* is both highly polished and nitrogen-enriched (as recommended in Section J, Titanium Articular Surface Coatings, of *Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented; Guidance for Industry and FDA*) to limit wear of the apposing *Bearings A and B* upon which it articulates.

The proximal portion of the *ulnar stem* is covered with plasma spray, which is contained within the Coatings Characterization of Orthopedic Titanium 6Al4V Coatings Material Master File (FDA Ref: MAF-652, Letter of Authorization can be found in Section 22). The *plasma spray region* is designed to increase the coefficient of friction between the implant and the bone cement, thereby improving anti-rotational stability and aiding in resistance to movement of the *ulnar stem* with respect to the ulna.

The *ulnar component* is side-specific, meaning that there is a left *ulnar component* and a right *ulnar component* available for every size offering.

Humeral Bearing-A

The *Humeral Bearing-A* is made from Vivacit-E™ (Vitamin E [α-tocopherol] stabilized, highly crosslinked ultra-high molecular weight polyethylene), which is contained within the Vitamin E Stabilized HXPE Material Master File authored by Zimmer (FDA Ref: MAF-1868). *Humeral bearing-A* is designed to articulate against the *ulnar component* throughout most of the humeroulnar joint range of motion, and has the following major design features: *concave articulation surface, anterior and posterior ridges*, a *peg*, four *peripheral bumps* and *medial and lateral rails*.

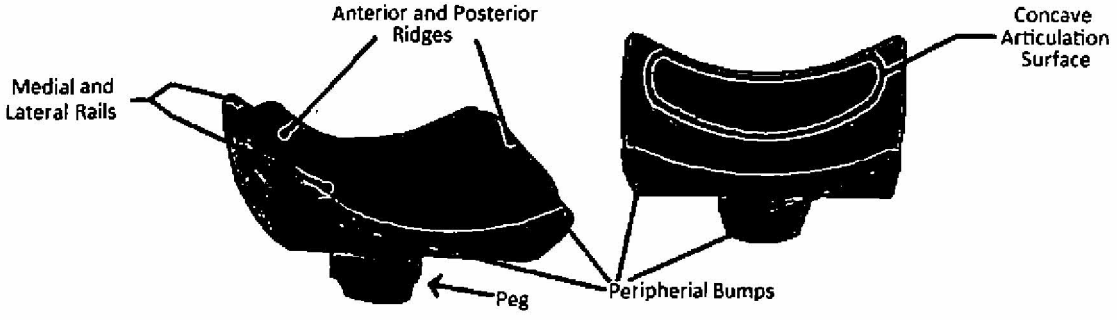

Image 11.7: Humeral Bearing-A, major design features

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The *humeral bearing-A concave articulation surface* is intended to (along with the articulation surface of the *ulnar bearings-B*) allow for load sharing from the ulnar component onto *humeral bearing-A* throughout most of the range of motion of the humeroulnar joint. The *posterior ridge* specifically supports high-flexion motions (see Image 11.8, below). The *humeral bearing-A anterior ridge* is symmetrical to the *posterior ridge* in order to remove the human factors issue of having to discern anterior from posterior when assembling *humeral bearing-A* to the *humeral component*: *humeral bearing-A* cannot be put in backwards, because it is symmetrical.

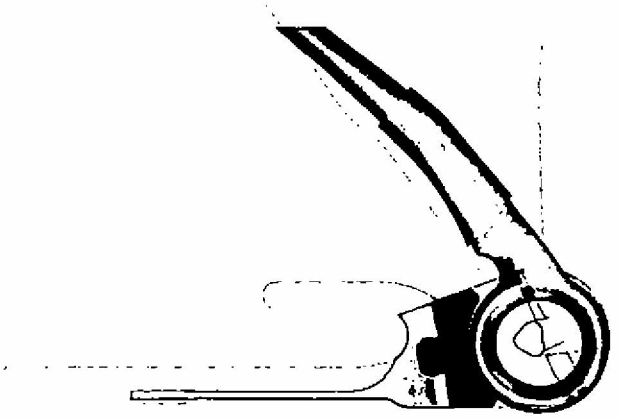

Image 11.8: Posterior Ridge of Humeral Bearing-A supporting high flexion of the ulnar component with respect to the humeral component

The *humeral bearing-A peg* is designed to mate to the hole at the proximal base of the *humeral yoke* with a press (not a snap) fit, which is intended to limit motion between *humeral bearing-A* and the *humeral yoke*.

The *humeral bearing-A* (four) *peripheral bumps* are designed to mate against the interior walls of the *humeral yoke* with a press-fit, which is intended to limit motion (and therefore backside wear) of the *humeral bearing-A* relative to the *humeral yoke*.

The humeral bearing-A *medial and lateral rails* are designed to allow clearance for (as opposed to a direct mate with) *ulnar bearings-B*, which directly mate to the *humeral yoke* and to the *axle pin*.

Note: The *humeral bearing-A* may also be referred to as "humeral bearing" and "bearing A" throughout this submission.

Ulnar Bearings-B

The *ulnar bearings-B* (two per implant assembly) are made from Vivacit-E™ (Vitamin E [α-tocopherol] stabilized, highly crosslinked ultra-high molecular weight polyethylene), which is contained within the Vitamin E Stabilized HXPE Material

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Master File authored by Zimmer (FDA Ref: MAF-1868). *Ulnar bearings-B* are designed to articulate against the *ulnar component* throughout the entire humeroulnar joint range of motion, and have the following major design features: *articulation surface, anti-rotation key, through-hole* and *compressible semi-circle.*

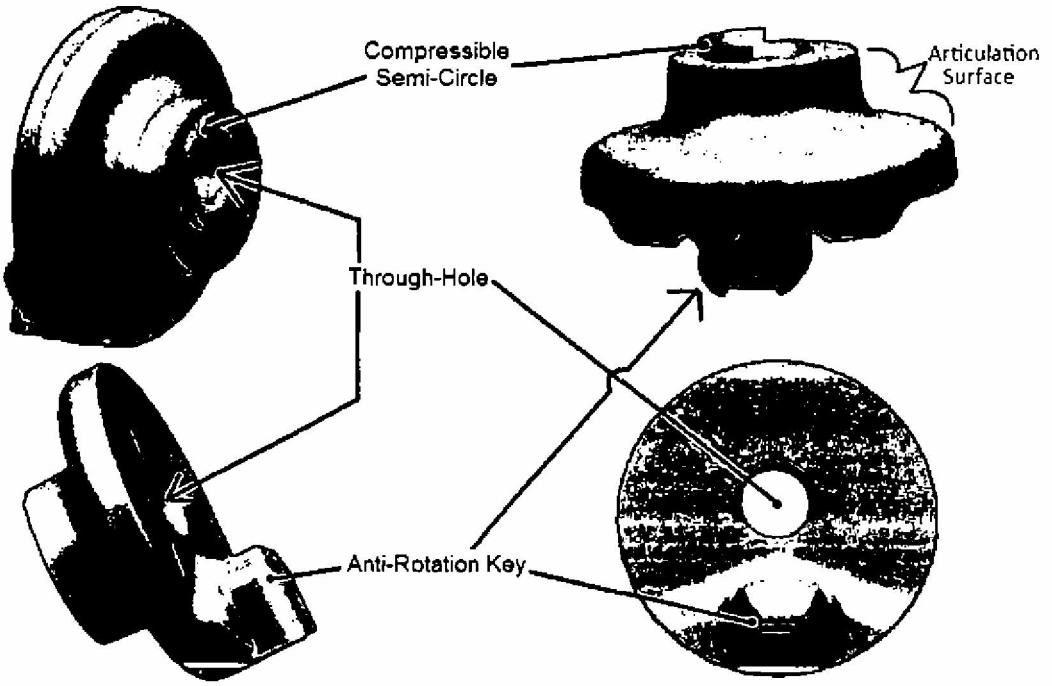

Image 11.9: Ulnar Bearings-B, major design features

The *ulnar bearings-B articulation surface* is intended to (along with the articulation surface of the *ulnar bearing-A*) allow for load sharing from the *ulnar component* onto *humeral bearing-B* throughout the range of motion of the humeroulnar joint.

The *ulnar bearings-B anti-rotation keys* mate into the *humeral yoke keyways* with a press-fit to limit translational and rotational motion of *ulnar bearings-B* with respect to the *humeral component.*

The *compressible semi-circle* of one *ulnar bearing-B* is designed to align with the *compressible semi-circle* of the second *ulnar bearing-B* such that a nearly full circle is created. This design feature is intended to ensure proper alignment of *ulnar bearings-B* with respect to each other (during assembly of *ulnar bearings-B* to the *axle pin* using the *ulnar bearing assembly tool*) and, after proper assembly to the *axle pin*, to the *humeral yoke keyways*. Due to the fact that the *compressible semi-circle* is more easily deformed than the broad, apposing faces of *ulnar bearings-B*, it creates a press-fit between the *ulnar bearings-B* and between each *ulnar bearing-B* and the apposing interior walls of the *humeral yoke*. This press-fit is intended to limit mediolateral motion of the *ulnar bearings-B* along the *axle-pin*, thereby limiting backside wear of the *ulnar bearings-B.*

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The *ulnar bearings-B through-hole* mates around the *axle pin* with a press-fit intended to limit motion of *ulnar bearings-B* with respect to the *axle pin*, and thus limit backside wear of *ulnar bearings-B*. The position of the *through-hole* is eccentric (with respect to the outer diameter of *ulnar bearings-B*) in order to place the largest cross-section of Vivacit-E™ material in opposition to the highest loads (Joint Reaction Forces, JRFs) induced throughout the flexion-extension cycle of the humeroulnar joint (see image 11.10, below).

Note: The *ulnar bearings-B* do NOT mate to or in any way interface with the *humeral screws*.

Note: The *ulnar bearings-B* may also be referred to as "ulnar bearing(s)" and "bearing(s) B" throughout this submission.

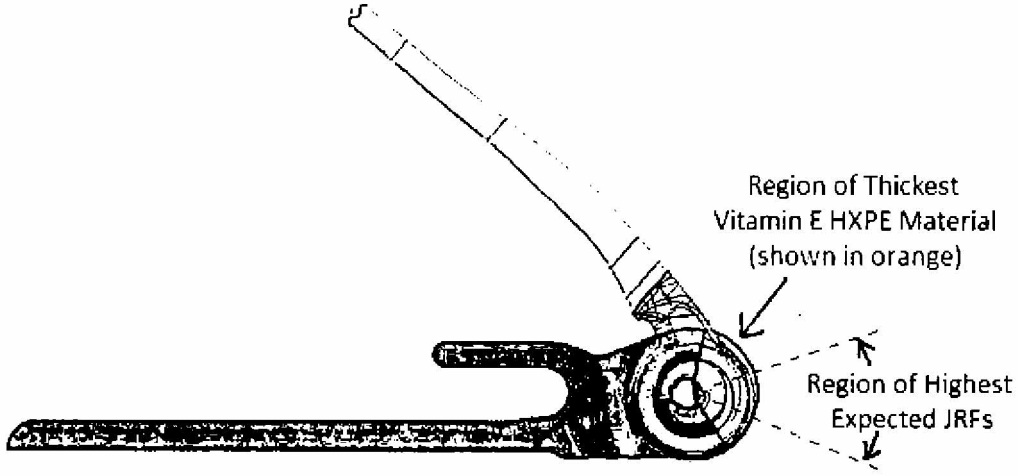

Image 11.10: Thickest Vitamin E HXPE placement to oppose highest JRFs

Axle Pin

The *axle pin* is made from *Zimaloy* (Cobalt-Chromium-Molybdenum Alloy), is designed to remain in a fixed position (not translate nor rotate) throughout the entire humeroulnar joint range of motion, and has the following major design feature: *v-groove*.

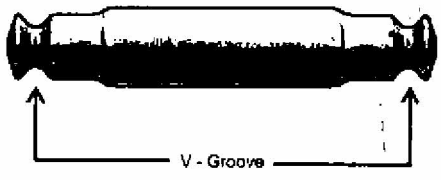

Image 11.11: Axle Pin, major design feature

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The *v-groove* is designed to mate with the taper of the *humeral screws* that, upon screw thread engagement in the *humeral yoke*, rigidly compresses the *axle pin* against the *humeral yoke*.

Additionally, the *axle pin* is designed to rigidly mate with *ulnar bearings-B*, the *humeral screws* and the *humeral yoke*, creating a rigid assembly along which joint reaction forces are intended to be shared.

Note: The *axle-pin* may also be referred to as "axle" throughout this submission.

Humeral Screws

The *humeral screws* (two per implant assembly) are made from *Zimaloy* (Cobalt-Chromium-Molybdenum Alloy), are designed to remain in a fixed position throughout the entire humeroulnar joint range of motion, and have the following major design features: *headless*, *threads*, *pilot* and *taper*.

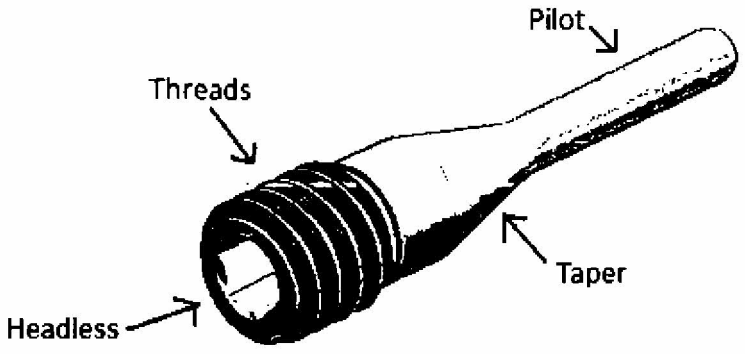

Image 11.12: Humeral Screws, major design feature

The *humeral screw threads* engage with threads of the *humeral yoke* while the *humeral screw pilot* engages a hole in the wall of the *humeral yoke* and the *humeral screw taper* engages with the *axle pin v-groove*, compressing the ends of the *axle pin* against the *v-groove* at the base of the *humeral yoke keyway*.

The *humeral screws* are *headless*, a feature that allows the *humeral screws* to countersink into the *humeral yoke*, which is intended to ensure the constant application of a clamp-load to the *axle-pin* and to avoid soft tissue impingement or irritation associated with a protruding screw head.

Note: While the *humeral screws* are designed to apply a consistent clamp-load to the *axle pin*, they are *not* directly loaded by any compressive joint reaction force (JRF) during the flexion-extension cycle (this design feature is intended to avoid screw back-out by not allowing any complete transverse load-reversal across the *humeral screw threads*). Instead, compressive JRFs are transmitted from the *ulnar implant*

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component to the *ulnar bearings-B* to the *axle pin* to the *v-grooves* at the base of the *humeral yoke keyways* and finally throughout the *humeral component*. See Zimmer Research Report ZRR_WA_2598_12, *New Zimmer Total Elbow Prosthesis Modular Connection Fatigue Testing* for a more detailed explanation.

System Compatibility

No Zimmer Nexel Total Elbow component is compatible with any device outside the Zimmer Nexel Total Elbow system.

Size Interchangeability

All Zimmer Nexel Total Elbow *humeral component* sizes are designed to mate with all Zimmer Nexel Total Elbow *ulnar component* sizes. The *axle pin* size 4, *humeral bearing-A* size 4, and *ulnar bearings-B* size 4 are designed to mate with all size 4 *humeral components*. The *axle pin* size 5/6, *humeral bearing-A* size 5/6, and *ulnar bearings-B* size 5/6 are designed to mate with all size 5 and size 6 *humeral components*. The *humeral screws* are designed to mate with all Zimmer Nexel Total Elbow *humeral components* and *axle pin* sizes.

Engineering Drawings

Representative engineering drawings for the proposed device are included at the end of this section.

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Catalog Numbers

All catalog numbers for the Zimmer Nexel Total Elbow are listed below.

Catalog Number	Description
00-8400-014-07	Zimmer Nexel Total Elbow - Ulnar Stem, Size 4, 75 mm, Left
00-8400-014-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 4, 115 mm, Left
00-8400-024-07	Zimmer Nexel Total Elbow - Ulnar Stem, Size 4, 75 mm, Right
00-8400-024-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 4, 115 mm, Right
00-8400-015-07	Zimmer Nexel Total Elbow - Ulnar Stem, Size 5, 75 mm, Left
00-8400-015-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 5, 115 mm, Left
00-8400-025-07	Zimmer Nexel Total Elbow - Ulnar Stem, Size 5, 75 mm, Right
00-8400-025-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 5, 115 mm, Right
00-8400-016-09	Zimmer Nexel Total Elbow - Ulnar Stem, Size 6, 90 mm, Left
00-8400-016-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 6, 115 mm, Left
00-8400-026-09	Zimmer Nexel Total Elbow - Ulnar Stem, Size 6, 90 mm, Right
00-8400-026-11	Zimmer Nexel Total Elbow - Ulnar Stem, Size 6, 115 mm, Right
00-8400-044-10	Zimmer Nexel Total Elbow - Humeral Stem, Size 4, 100 mm
00-8400-044-15	Zimmer Nexel Total Elbow - Humeral Stem, Size 4, 150 mm
00-8400-045-10	Zimmer Nexel Total Elbow - Humeral Stem, Size 5, 100 mm
00-8400-045-15	Zimmer Nexel Total Elbow - Humeral Stem, Size 5, 150 mm
00-8400-055-15	Zimmer Nexel Total Elbow - Humeral Stem, Long Flange, Size 5, 150 mm
00-8400-055-20	Zimmer Nexel Total Elbow - Humeral Stem, Long Flange, Size 5, 200 mm
00-8400-046-10	Zimmer Nexel Total Elbow - Humeral Stem, Size 6, 100 mm
00-8400-046-15	Zimmer Nexel Total Elbow - Humeral Stem, Size 6, 150 mm
00-8400-056-15	Zimmer Nexel Total Elbow - Humeral Stem, Long Flange, Size 6, 150 mm
00-8400-056-20	Zimmer Nexel Total Elbow - Humeral Stem, Long Flange, Size 6, 200 mm
Kit # 00-8400-094-00 00-8400-194-01 00-8400-194-02 00-8400-194-04	*Zimmer Nexel Total Elbow - Articulation Kit, Size 4* Kit Contents: 1 Humeral Bearing-A Size 4 2 Ulnar Bearings- B Size 4 1 Axle Pin Size 4
Kit # 00-8400-095-00 00-8400-195-01 00-8400-195-02 00-8400-195-04	*Zimmer Nexel Total Elbow - Articulation Kit, Size 5/6* Kit Contents: 1 Humeral Bearing-A Size 5/6 2 Ulnar Bearings- B Size 5/6 1 Axle Pin Size 5/6
Kit # 00-8400-090-00 00-8400-190-00	*Zimmer Nexel Total Elbow - Humeral Screw Kit* Kit Contents: 2 Humeral Screws

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Materials

The *humeral and ulnar components* are made of wrought *Tivanium* alloy (Ti-6Al-4V) and are titanium plasma sprayed (on regions specified in the engineering drawings at the end of this section). The *bearings A and B* are made of *Vitamin E HXPE* (Vitamin E Highly Crosslinked Polyethylene). The *axle pin* and *humeral screws* are made of *Zimaloy* (Cobalt-Chromium-Molybdenum Alloy).

The following tests contained within the Material Master File for Vitamin E Stabilized Highly Crosslinked Polyethylene (Master File MAF-1868) are applicable to usage in elbow devices and support substantial equivalence of the Vitamin E Stabilized HXPE material when used in elbow devices:

Report Number	Report Name	Master File Location
ZRR_WA_2401_11 Rev. 2	TESTING OF VITAMIN E HIGHLY CROSSLINKED POLYETHYLENE PROPERTIES PER ASTM F2759-09	Amendment 02, Exhibit B
N102082	NAMSA - TOXICOLOGICAL RISK ASSESSMENT	Volume 1, Page 54
T0118_913/S	13 WEEK SYSTEMIC TOXICITY STUDY IN RATS FOLLOWING SUBCUTANEOUS IMPLANTATION	Volume 1, Page 86
V0014_130	CYTOTOXICITY STUDY USING THE ISO ELUTION METHOD	Volume 1, Page 76
V0023_211	BACTERIAL REVERSE MUTATION STUDY - EXTRACTS	Volume 1, Page 108
V0573_000/S	GENOTOXICITY: MOUSE LYMPHOMA ASSAY	Volume 1, Page 125
T0566_500, T0566_501	MOUSE PERIPHERIAL BLOOD MICRONUCLEUS STUDY	Volume 1, Pae 147
T1251_800	ISO INTRACUTANEOUS STUDY IN RABBITS	Volume 1, Page 179
T1261_300	ISO GUINEA PIG MAXIMIZATION SENSITIZATION TEST	Volume 1, Page 189
T1250_812	ISO MUSCLE IMPLANTATION STUDY IN RABBITS - 12 WEEKS	Volume 1, Page 205
T1250_802	ISO MUSCLE IMPLANTATION STUDY IN RABBITS - 2 WEEKS	Volume 1, Page 217
ZRR_WA_2338_11	VITAMIN E HIGHLY CROSSLINKED POLYETHYLENE SHELF LIFE STUDY	Volume 1, Page 230
T02625-500	ISO SYSTEMIC TOXICITY STUDY IN MICE	Volume 1, Page 245
T0118_926	26 WEEK SYSTEMIC TOXICITY STUDY IN RATS FOLLOWING SUBCUTANEOUS IMPLANTATION	Volume 1, Page 256
ZRR_WA_2424_11	EVALUATION OF VITAMIN E DOPED AND CROSSLINKED UHMWPE WEAR DEBRIS IN THE RABBIT KNEE FOLLOWING PERCUTANEOUS INJECTION	Amendment 01, Page 9

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Report Number	Report Name	Master File Location
10T_60283_02	BIOLOGICAL RESPONSE TO WEAR DEBRIS Note: The particulate study was done to detect local and systemic response to vitamin E grafted UHMWPE. A rabbit model which is widely accepted was used. The particulates were produced from production materials and have size distribution that is representative of those that have been isolated from tissues harvested during hip or knee revision surgeries. The particles were injected directly into the knee capsule of the animals. This study was not focused on any particular implant or device. The emphasis was on inflammatory response to the particulates. The study covered all devices that generate particulates.	Volume 2, Page 243
ZRR_WA_2409_11	VIATMIN E STABILIZED HIGHLY CROSSLINKED POLYETHYLENE EXTENDED AGING STUDY	Volume 2, Page 394
ZRR_WA_2373_11	ENVIRONMENTAL STRESS CRACKING OF VITAMIN E, LONGEVITY, CONVENTIONAL UHMWPE	Volume 2, Page 422
ZRR_WA_2403_11	VITAMIN E STABILIZED HIGHLY CROSSLINKED POLYETHYLENE- EXTRACTABILITY STUDY	Volume 2, Page 441
ZRR_WA_2412_11	VITAMIN E STABILIZED HIGHLY CROSSLINKED POLYETHYLENE- PRESSURE INDUCED LEACHING	Volume 2, Page 492
ZRR_WA_2382_11	VITAMIN E STABILIZED HIGHLY CROSSLINKED POLYETHYLENE- TRANSFORMATION PRODUCTS EVALUATION BY HPLC AND GC	Volume 2, Page 507
ZRM_WA_0293_11	LAMELLAE THICKNESS	Volume 2, Page 566
ZRM_WA_0277_11	MOLECULAR WEIGHT	Volume 2, Page 578
CPG REPORT_ 11622_1	GC/MS ANALYSIS OF UHMWPE	Amendment 02, Exhibit A

Surface Characteristics

The *eye* of the *ulnar component* is treated with a nitrogen ion implantation (also known as nitriding) process (to increase *Tivanium* alloy surface hardness) on the region specified in the engineering drawings at the end of this section.

The articulating surfaces of the *ulnar component* are polished to an R_a value of 8 microinches or less and the articulating surfaces of the *bearings A and B* are machined to an R_a value of 32 microinches or less to provide for smooth articulating surfaces.

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Mechanism of Action

The Zimmer Nexel Total Elbow implant assembly is a semi-constrained prosthesis designed to allow anatomic reconstruction of the humeroulnar joint with the natural change in humeroulnar joint center of rotation throughout the flexion/extension arc based on research presented in the Zimmer Research Report ZRR_WA_2476_11, *Biomechanics Rationale for the Loading of Total Elbow Prosthesis During In Vitro Simulations*. See table below for range of motion details.

	Feature		Proposed Device: The Zimmer Nexel Total Elbow
Range of Motion (defined in terms of Ulnar Component movement with respect to Humeral Component)	Varus/Valgus Angular Laxity		Neutral to Maximum Varus: (b) Neutral to Maximum Valgus: (4) Total Included Angle: (b)
	Internal/External Rotational Laxity		Neutral to Maximum Internal Rotation: (b) Neutral to Maximum External Rotation: (4) Total Included Angle: (b)
	Pistoning	Proximal/Distal Translational Laxity	Neutral to Maximum Proximal: (b)(4) Neutral to Maximum Distal: Total Proximal/Distal Laxity:
	Pistoning	Anterior/Posterior Translation Laxity	Neutral to Maximum Anterior: Neutral to Maximum Posterior: Total Anterior/Posterior Laxity:
	Medial/Lateral Translation Laxity		Neutral to Maximum Medial: Neutral to Maximum Lateral: Total Medial/Lateral Laxity:
	Flexion/Extension Range (defined in terms of degrees flexion)		All Humeral and Ulnar size combinations: (b)(4)

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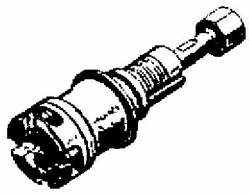
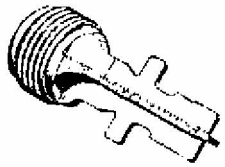
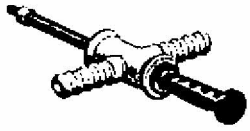
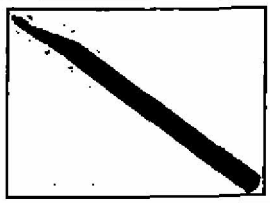
Surgical Instrumentation Unique to the Device

Following are the instruments unique to the Zimmer Nexel Total Elbow. These are Class II accessories to the device. Applicable material standards are listed in a table at the end of this section.

The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
(Table Continued on Next Page)

Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-002-00	T-Handle	17-4 SS 303 SS 420 SS 316 SS	yes		Quick-connect handle for use with humeral and ulnar rasps.
00-8401-008-00	Reciprocating Saw Adapter	303 SS 420 SS 316 SS	yes		Adapter to connect humeral and ulnar rasps to a compatible large bone reciprocating saw via the single use connector.
00-8401-008-01	Single Use Connector	455 SS	yes, skin only		Connects the reciprocating saw adaptor to a compatible large-bone reciprocating saw.
00-8401-009-00	Slide Hammer	17-4 SS 304 SS 17-4 SS	yes		Mates with humeral and ulnar stem extractors to deliver impact blows when extractor component is attached to the implant.
00-8401-018-00	Ulnar Bearing Tamp	17-4 SS	yes		To compress the articulating assembly (ulnar bearings and axle pin) into the humeral implant. (An alternate instrument to the articulation inserter.)
00-8401-012-04	Trephine Stabilizer, Size 4	17-4 SS	yes		Guides the finishing cut of the trephine through the anterior aspect of the humerus.
00-8401-012-05	Trephine Stabilizer, Size 5	17-4 SS	yes		

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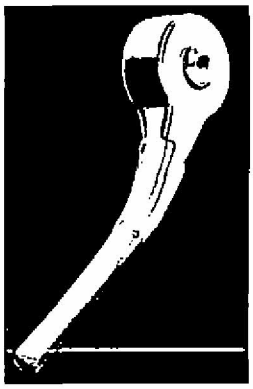
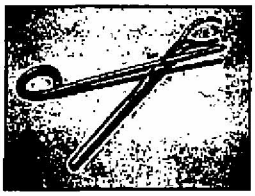
Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-014-07	Ulnar Provisional, Size 4, 75 mm, Left	17-4 SS	yes		To assess the bone preparation of the ulnar medullary canal, and to allow an intraoperative range of motion.
00-8401-014-11	Ulnar Provisional, Size 4, 115 mm, Left	17-4 SS	yes		
00-8401-015-07	Ulnar Provisional, Size 5, 75 mm, Left	17-4 SS	yes		
00-8401-015-11	Ulnar Provisional, Size 5, 115 mm, Left	17-4 SS	yes		
00-8401-016-09	Ulnar Provisional, Size 6, 90 mm, Left	17-4 SS	yes		
00-8401-016-11	Ulnar Provisional, Size 6, 115 mm, Left	17-4 SS	yes		
00-8401-024-07	Ulnar Provisional, Size 4, 75 mm, Right	17-4 SS	yes		
00-8401-024-11	Ulnar Provisional, Size 4, 115 mm, Right	17-4 SS	yes		
00-8401-025-07	Ulnar Provisional, Size 5, 75 mm, Right	17-4 SS	yes		
00-8401-025-11	Ulnar Provisional, Size 5, 115 mm, Right	17-4 SS	yes		
00-8401-026-09	Ulnar Provisional, Size 6, 90 mm, Right	17-4 SS	yes		
00-8401-026-11	Ulnar Provisional, Size 6, 115 mm, Right	17-4 SS	yes		
00-8401-019-00	Articulation Inserter	17-4 SS	yes		To compress the articulating assembly (ulnar bearings and axle pin) and ulnar implant into the humeral implant. Also, to compress the humeral bearing into the humeral implant. (This is an alternate instrument to the ulnar bearing tamp and the humeral bearing driver.)
00-8401-028-00	Ulnar Stem Inserter	Radel	yes		To transmit force to insert the ulnar implant without damaging the articular surface.

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The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
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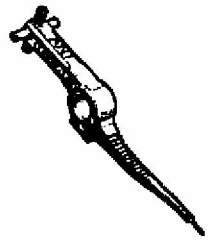
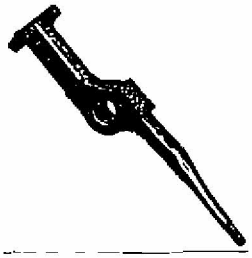
Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-029-00	Implant Extractor Hook	17-4 SS	yes		To transmit force from the slide hammer to an implanted ulnar implant or humeral implant to facilitate their removal. The extractor hook is attached to the slide hammer by a threaded connection.
00-8401-033-01	Ulnar Rasp, Pilot, Left	17-4 SS	yes		Removes bone from the ulnar medullary canal and olecranon and shapes the medullary canal to create a precise geometry for a size-matched ulnar implant. Can be mated to the reciprocating saw adaptor or to the T-handle.
00-8401-033-02	Ulnar Rasp, Pilot, Right	17-4 SS	yes		
00-8401-034-01	Ulnar Rasp, Size 4/5, Left	17-4 SS	yes		
00-8401-034-02	Ulnar Rasp, Size 4/5, Right	17-4 SS	yes		
00-8401-036-01	Ulnar Rasp, Size 6, Left	17-4 SS	yes		
00-8401-036-02	Ulnar Rasp, Size 6, Right	17-4 SS	yes		
00-8401-039-00	Ulnar Clearance Template	17-4 SS	yes		To check for adequate bone removal on the medial and lateral sides of the ulna for clearance for the articulation insertion instruments.

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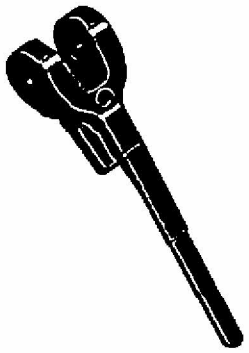
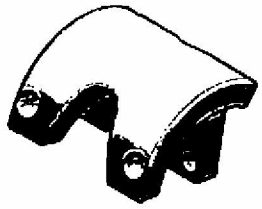
The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
(Table Continued from Previous Page, Continued on Next Page)

Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-044-10	Humeral Provisional, Size 4, 100 mm	17-4 SS	yes		Dimensionally represents the humeral implant to help assess the preparation of the humeral medullary canal, and to intraoperatively check range of motion.
00-8401-044-15	Humeral Provisional, Size 4, 150 mm	17-4 SS	yes		
00-8401-045-10	Humeral Provisional, Size 5, 100 mm	17-4 SS	yes		
00-8401-045-15	Humeral Provisional, Size 5, 150 mm	17-4 SS	yes		
00-8401-046-10	Humeral Provisional, Size 6, 100 mm	17-4 SS	yes		
00-8401-046-15	Humeral Provisional, Size 6, 150 mm	17-4 SS	yes		
00-8401-055-15	Humeral Provisional, Long Flange, Size 5, 150mm	17-4 SS	yes		
00-8401-055-20	Humeral Provisional, Long Flange, Size 5, 200mm	17-4 SS	yes		
00-8401-056-15	Humeral Provisional, Long Flange, Size 6, 150mm	17-4 SS	yes		
00-8401-056-20	Humeral Provisional, Long Flange, Size 6, 200mm	17-4 SS	yes		
00-8401-058-04	Humeral Stem Inserter, Size 4	17-4 SS	yes		To insert the humeral implant into the humeral canal without damaging the humeral bearing.
00-8401-058-05	Humeral Stem Inserter, Size 5/6	17-4 SS	yes		
00-8401-059-04	Humeral Extractor Plate, Size 4	17-4 SS	yes		To transmit force from slide hammer to humeral implant in order to facilitate removal. Extractor plate is attached to humeral implant by the humeral extractor screws.
00-8401-059-05	Humeral Extractor Plate, Size 5/6	17-4 SS	yes		

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The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
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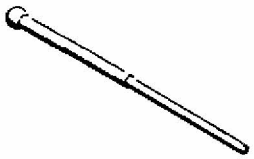
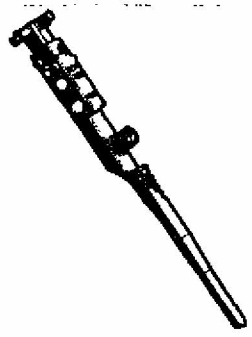
Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-060-00	Humeral Awl Reamer	17-4 SS	yes		To open the humeral medullary canal. Also, provides a means of ensuring the trochlear resection is adequate to accept subsequent humeral rasps.
00-8401-061-00	I/E Alignment Rod	17-4 SS	yes		To assess and adjust, if necessary, the internal/external rotation of the humeral and ulnar rasps.
00-8401-064-00	Humeral Rasp, Pilot	17-4 SS	yes		Removes bone from the humeral medullary canal to create a precise geometry for a size-matched humeral implant. Humeral rasps also used to orient and securely support the humeral cut guide, and to guide the trephine cut.
00-8401-064-10	Humeral Rasp, Size 4, 100 mm	17-4 SS	yes		
00-8401-064-15	Humeral Rasp, Size 4, 150 mm	17-4 SS	yes		
00-8401-065-10	Humeral Rasp, Size 5, 100 mm	17-4 SS	yes		
00-8401-065-15	Humeral Rasp, Size 5, 150 mm	17-4 SS	yes		
00-8401-066-10	Humeral Rasp, Size 6, 100 mm	17-4 SS	yes		
00-8401-066-15	Humeral Rasp, Size 6, 150 mm	17-4 SS	yes		

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The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
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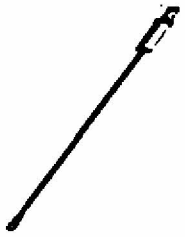
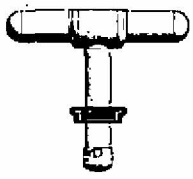
Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-070-45	Flexible Solid Reamer, 4.5 mm	13-8 SS	yes		To remove bone from the ulnar medullary canal. Connects to a surgical drill or reamer driver.
00-8401-070-05	Flexible Solid Reamer, 5 mm	13-8 SS	yes		
00-8401-072-01	Flexible Cannulated Reamer, 5.5 mm	13-8 SS	yes		Mates over the guide wire. Used to remove bone from the ulnar and humeral medullary canals. Connects to a surgical drill or reamer driver.
00-8401-072-02	Flexible Cannulated Reamer, 6 mm	13-8 SS	yes		
00-8401-072-03	Flexible Cannulated Reamer, 6.5 mm	13-8 SS	yes		
00-8401-072-04	Flexible Cannulated Reamer, 7 mm	13-8 SS	yes		
00-8401-072-05	Flexible Cannulated Reamer, 8 mm	13-8 SS	yes		
00-8401-072-06	Flexible Cannulated Reamer, 9 mm	13-8 SS	yes		
00-8401-072-07	Flexible Cannulated Reamer, 10 mm	13-8 SS	yes		
00-8401-072-08	Flexible Cannulated Reamer, 11 mm	13-8 SS	yes		
00-8401-072-09	Flexible Cannulated Reamer, 12 mm	13-8 SS	yes		
00-8401-074-00	Trephine, Size 4	17-4 SS 13-8 SS	yes		Removes bone from the distal humerus to accept a given size-matched humeral implant. Connects to a surgical drill.
00-8401-075-00	Trephine, Size 5/6	17-4 SS 13-8 SS	yes		
00-8401-078-00	Humeral Bearing Driver	17-4 SS	yes		To deliver a compressive force sufficient to fully seat the humeral bearing into the humeral implant when used with the humeral bearing driver pin. Also used to install a humeral bearing component into the humeral implant during a revision surgery. (This is an alternate instrument to the articulation inserter.)

EXEMPT FROM DISCLOSURE UNDER FOIA. Questions? Contact CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The Zimmer Nexel Total Elbow – Class II Accessories to the Implant
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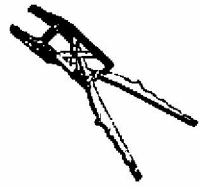
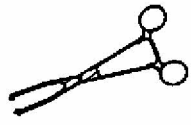
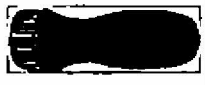
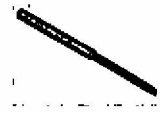
Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-079-00	Humeral Bearing Driver Pin	440A SS	yes		Subcomponent of the humeral bearing driver. Can also be used to aid in internal/external alignment of the ulnar provisionals.
00-8401-081-00	Ulnar Bearing Assembly Tool	17-4 SS 455 SS 316 SS	yes		To assemble the axle pin to ulnar bearings-B; and, to assemble the ulnar bearings-B onto the axle pin through the proximal head of the ulnar Implant. Performed by compressing the handle of the tool manually. To be used in situ.
00-8401-082-00	Humeral Bearing Placement Tool	420 SS 304 SS	yes		To place humeral bearing-A into the base of the humeral implant yoke.
00-8401-084-00	Humeral Screw Holder, Size 4	17-4 SS	yes		To securely hold the humeral screws and align the screws to a size-matched humeral implant.
00-8401-085-00	Humeral Screw Holder, Size 5/6	17-4 SS	yes		
00-8401-088-00	Humeral Screw Installation Driver Bit	440C SS LDPE	yes		Connects to the humeral screw installation driver to install the humeral screws into the humeral implant, and prevents the user from over-torquing the humeral screws. An alternative to the torque-limiting humeral screw driver, below. NOTE: *Cannot* mate with the humeral screw removal driver.
00-8401-089-00	Humeral Screw Removal Driver	455 SS 303 SS Silicone	yes		To remove the humeral screws from the humeral implant only when mated with the humeral screw removal driver bit. NOTE: Will *not* allow installation torque to be applied.
00-8401-091-00	Humeral Bearing Extractor	17-4 SS	yes		To remove the humeral bearing from the humeral implant.
00-8401-092-00	Articulation Extractor	17-4 SS	yes		To remove the articulation assembly (ulnar bearings and axle pin) and ulnar implant from the humeral implant.

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Catalog Number	Description	Material	Tissue Contact?	Image (not to scale)	Intended Use
00-8401-093-00	Humeral Extractor Screw	455 SS	yes		Attaches the humeral extractor plate to the humeral implant to facilitate humeral component extraction.
00-8401-097-00	Humeral Screw Removal Driver Bit	440C SS 316 SS	yes		Used with the humeral screw removal driver. NOTE: *Cannot* mate with the humeral screw installation driver.
00-8401-004-00	Humeral Cut Guide, Size 4	17-4 SS	yes		Connects to humeral rasps. Used to facilitate the creation of parallel cuts equidistant from the longitudinal axis of the rasp when used with a surgical blade.
00-8401-005-00	Humeral Cut Guide, Size 5/6	17-4 SS	yes		
00-8401-080-00	Torque-Limiting Humeral Screw Driver	440C SST Ultem	yes		To install and remove the humeral screws into and from the humeral implant. Prevents the user from over-torquing the humeral screws upon insertion. This instrument is intended to be used for a single surgery only.

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Surgical Instrumentation Not Unique to the Device

Following are the instruments not unique to the Zimmer Nexel Total Elbow. These are Class I instruments currently able to be used with other surgical devices cleared for market in the United States.

The Zimmer Nexel Total Elbow – Class I Instruments	
Catalog Number	Description
00-4812-035-00	Small Hex Screwdriver
47-2255-008-00	Sterile Ball Tip Guide Wire 2.4 x 70
31-8106-168-00	Ulnar Awl Reamer
00-4811-035-01	Humeral Screw Installation Driver
00-5049-053-00	Quick Use Curette

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Instrument Material Standards

The Zimmer Nexel Total Elbow: Instrument Material Standards	
Material	**Applicable Standards per Zimmer Engineering Specifications**
6061-T6 Aluminum	ASTM B209, ASTM B211, ASTM B221
13-8 SS	ASTM A484, ASTM A555, ASTM A564
17-4 SS	ASTM A484, ASTM F899
18-8 SS	ASTM A484, ASTM A555, ASTM A580
303 SS	ASTM F899
304 SS	ASTM A276, ASTM A484
316 SS	ASTM F899
316L SS	ASTM F138, ASTM F139, ASTM 1350, ISO 5832-1
420 SS	ASTM F899
440A SS	ASTM F899, ASTM A555
440C SS	ASTM F899
455 SS	ASTM F899, ISO 7153-1
Phenolic	No Standard Applicable
L 605 (Co-Cr-W-Ni alloy)	ASTM F90
LDPE	ASTM D1248
Radel	No Standard Applicable
Silicone	No Standard Applicable
Ultem	ASTM D5205

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Methods, Facilities and Controls

Method of Manufacturing

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Packaging

Humeral Stem

(b)(4)

The above listed materials are identical to those currently in use for Zimmer sterile implant packages with the only exception being that the configuration of the interior components correspond to the particular product being packaged.

Ulnar Stem

(b)(4)

The above listed materials are identical to those currently in use for Zimmer sterile implant packages with the only exception being that the configuration of the interior components correspond to the particular product being packaged.

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Articulation Kit

(b)(4)

The above listed materials are identical to those currently in use for Zimmer sterile implant packages with the only exception being that the configuration of the interior components correspond to the particular product being packaged.

Humeral Screw Kit

(b)(4)

The above listed materials are identical to those currently in use for Zimmer sterile implant packages. Only the configuration of the interior components changes to correspond to the particular product being packaged.

Pyrogenicity

This device is not labeled as nonpyrogenic. Per USP XXIII (161), requirements for specified endotoxin levels do not apply to orthopaedic implants.

Latex

There is no natural latex rubber in this product or its packaging.

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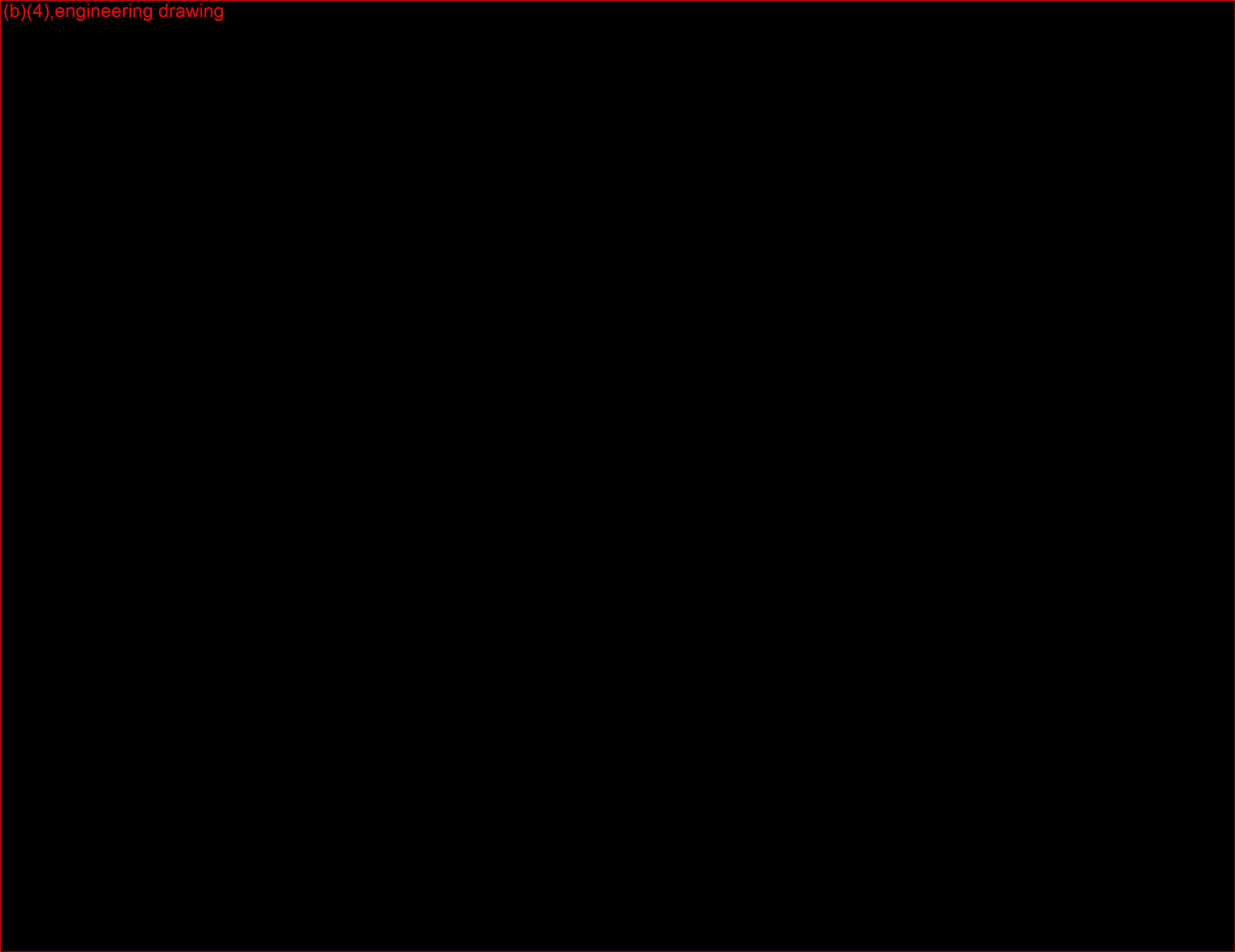
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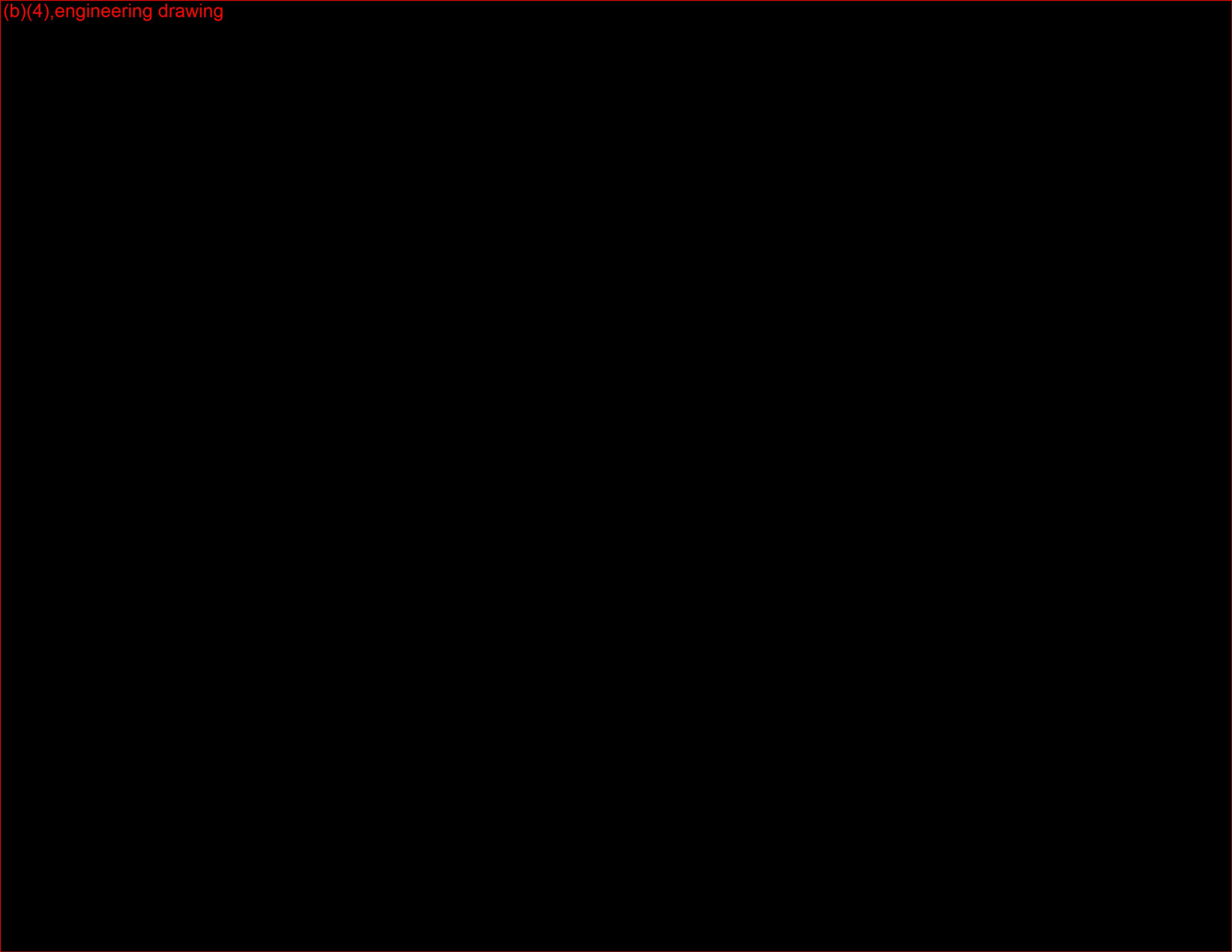
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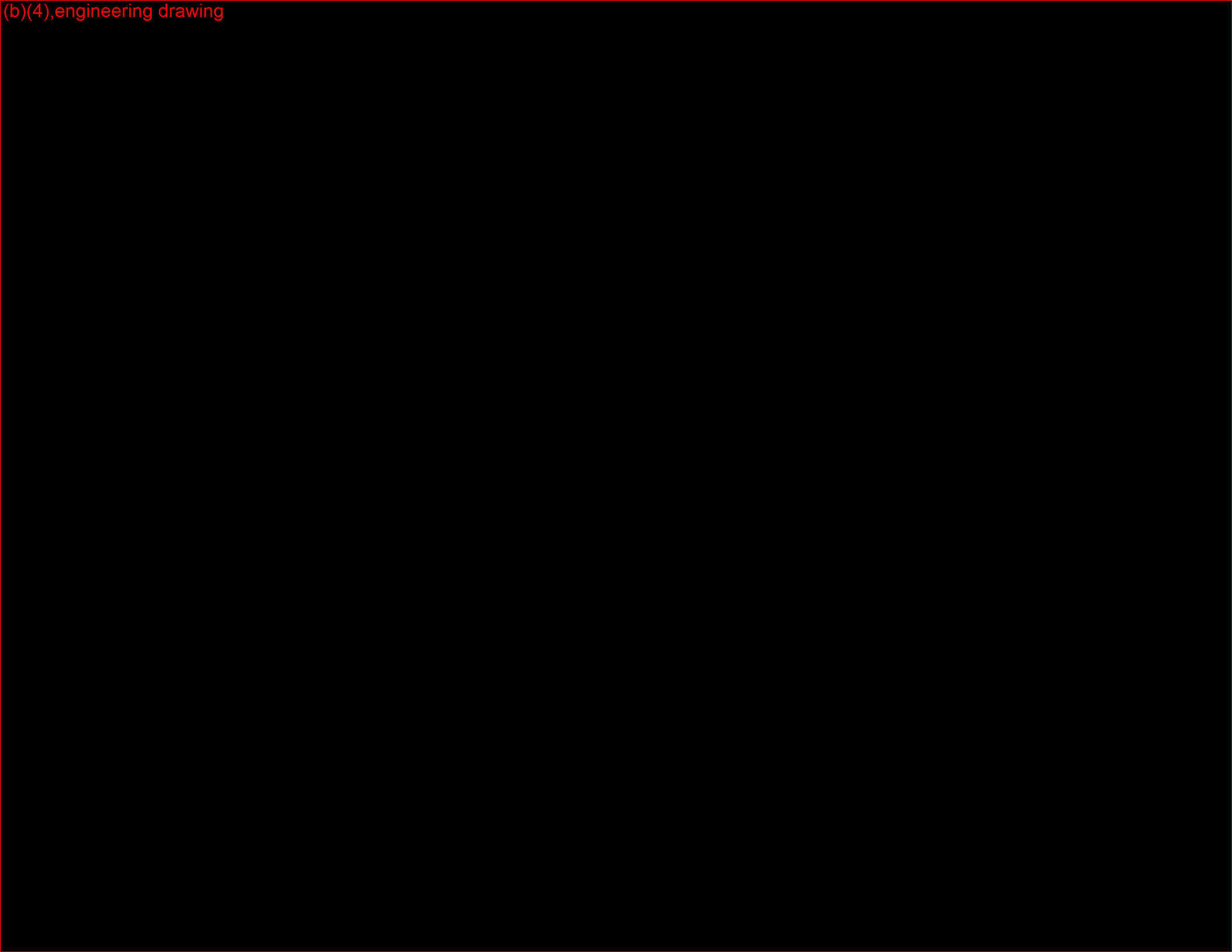
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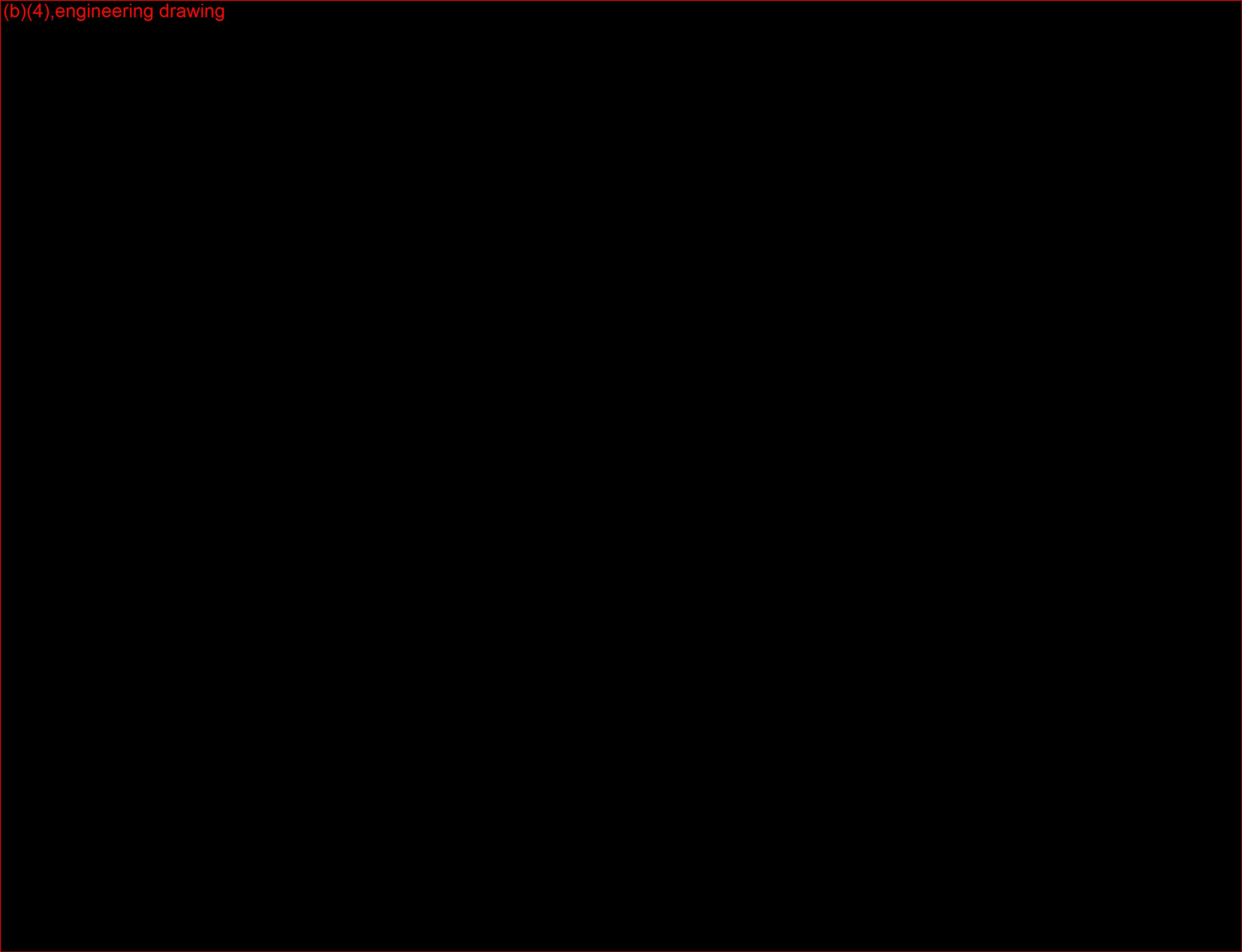
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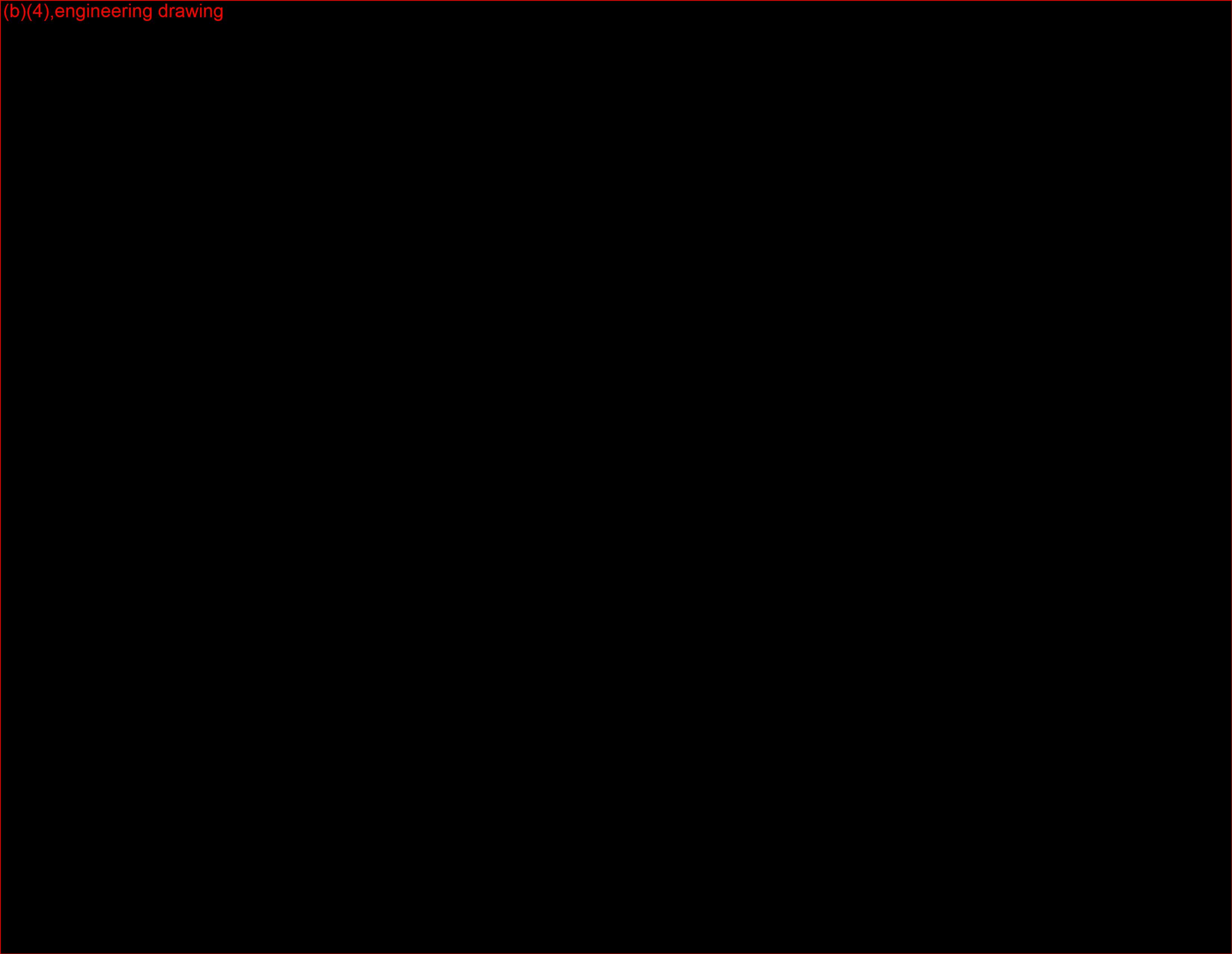
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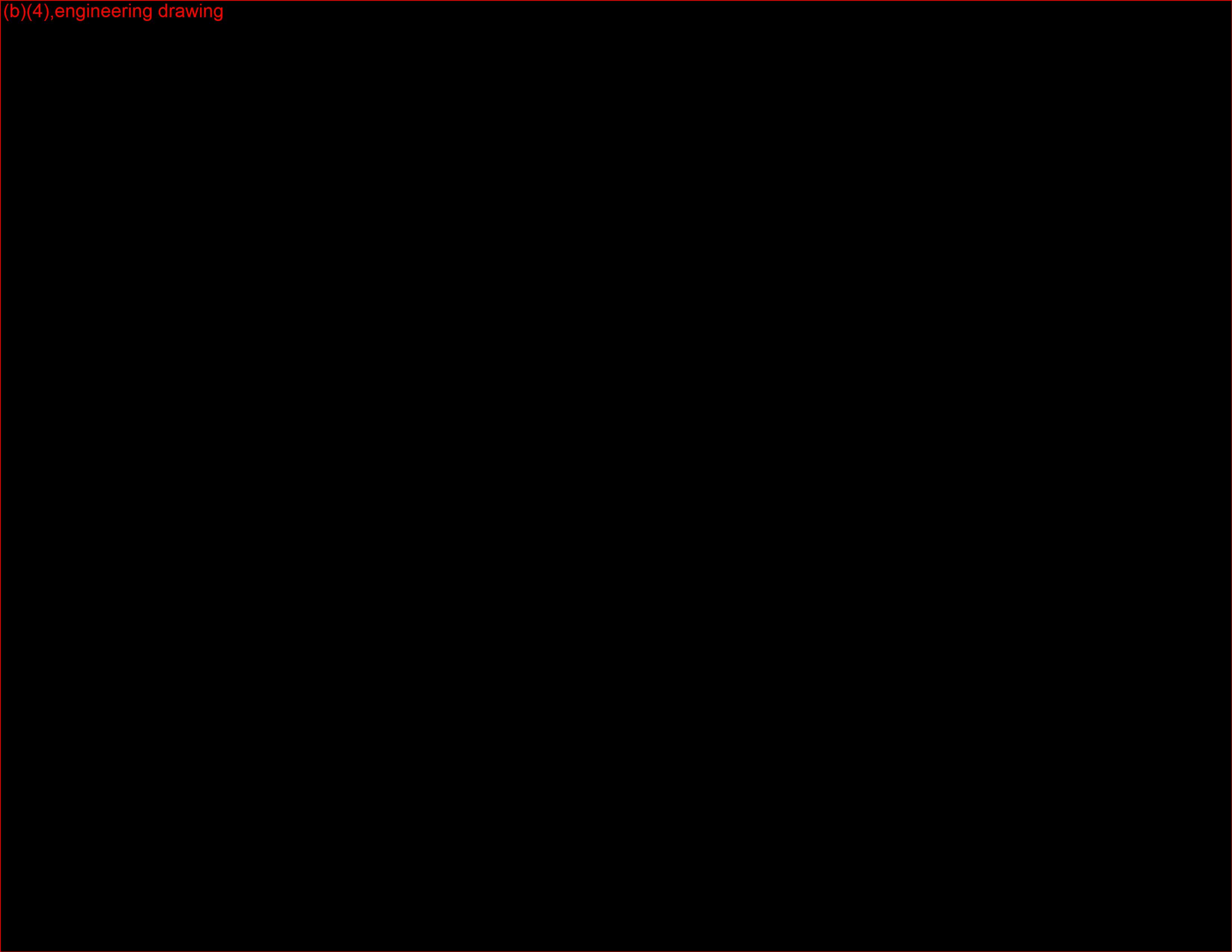
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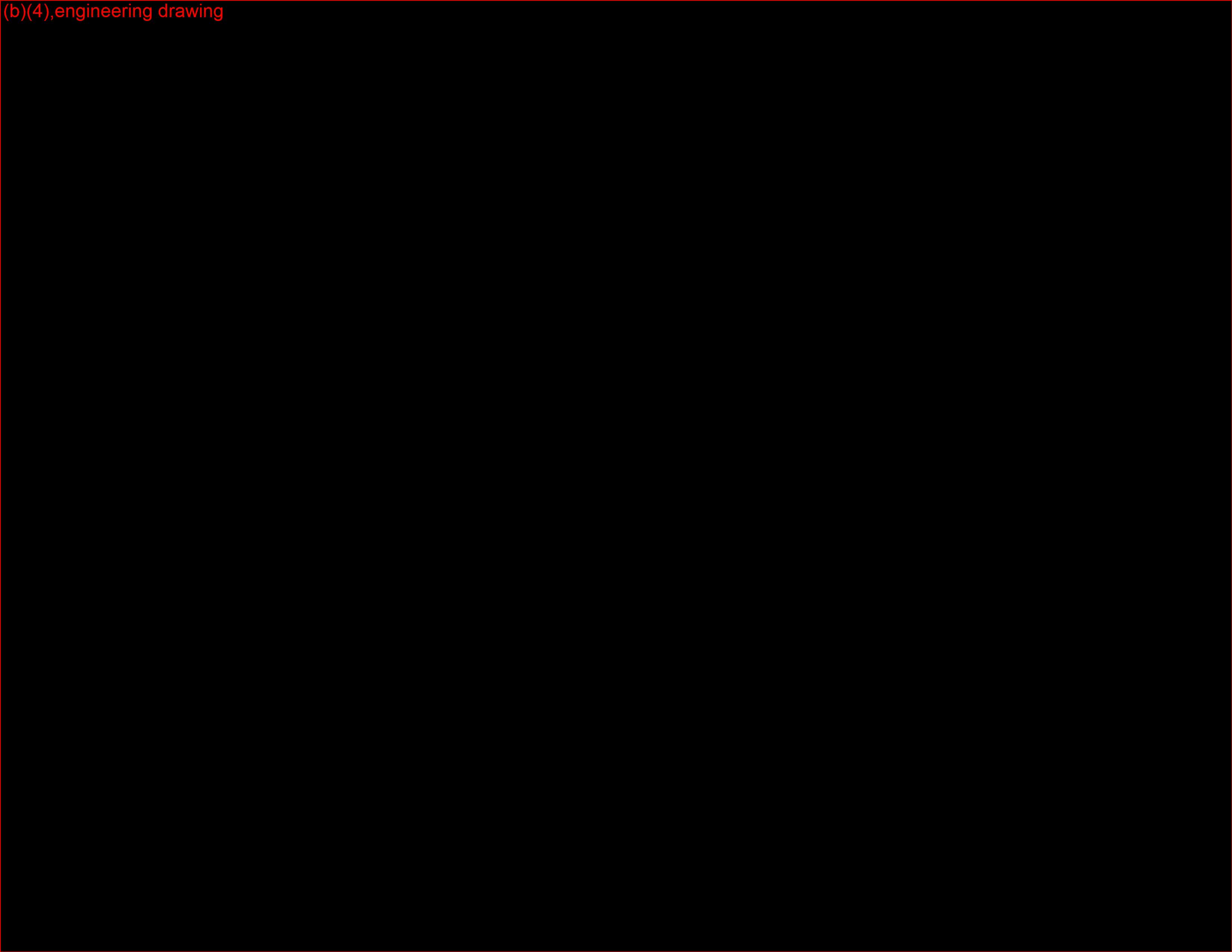
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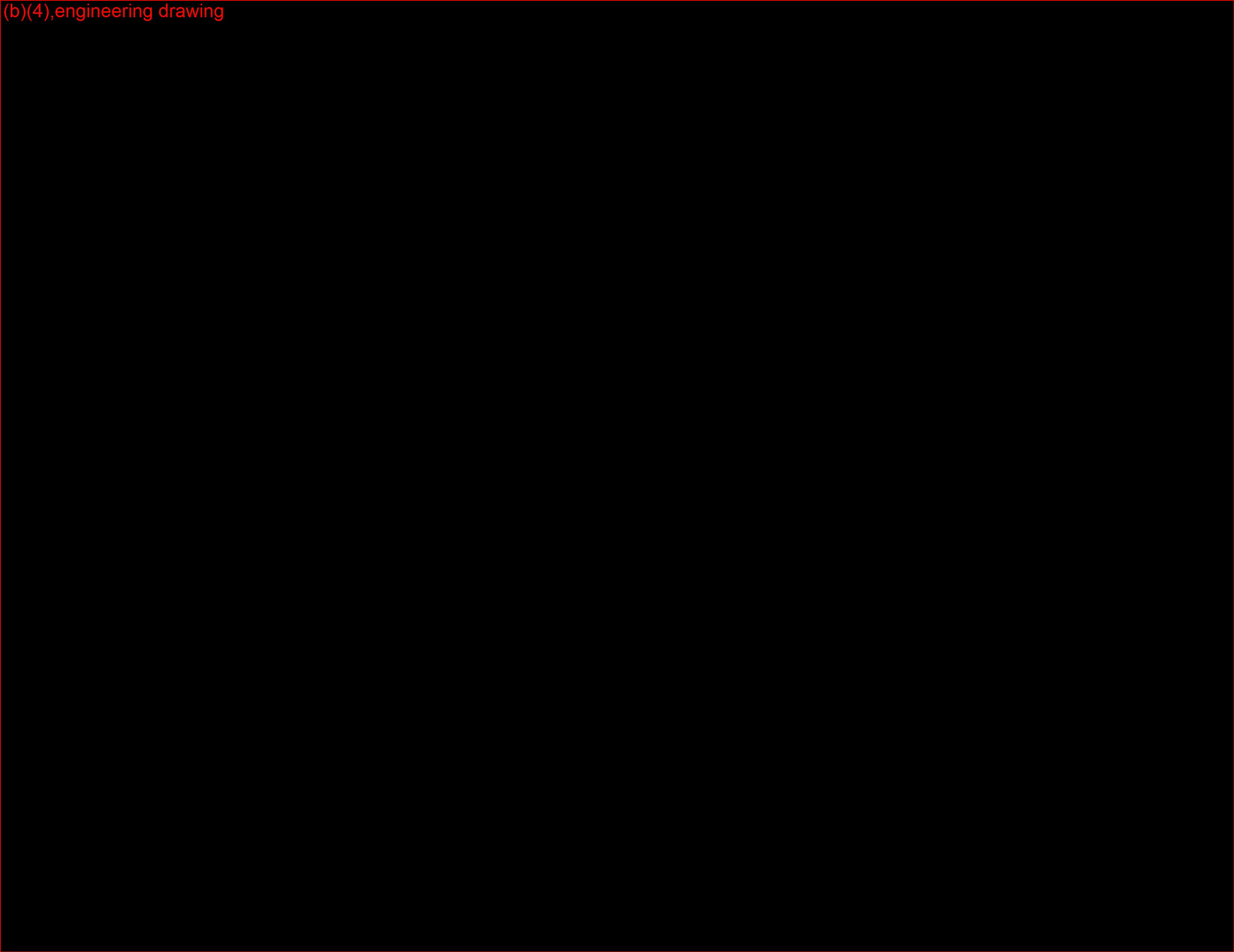
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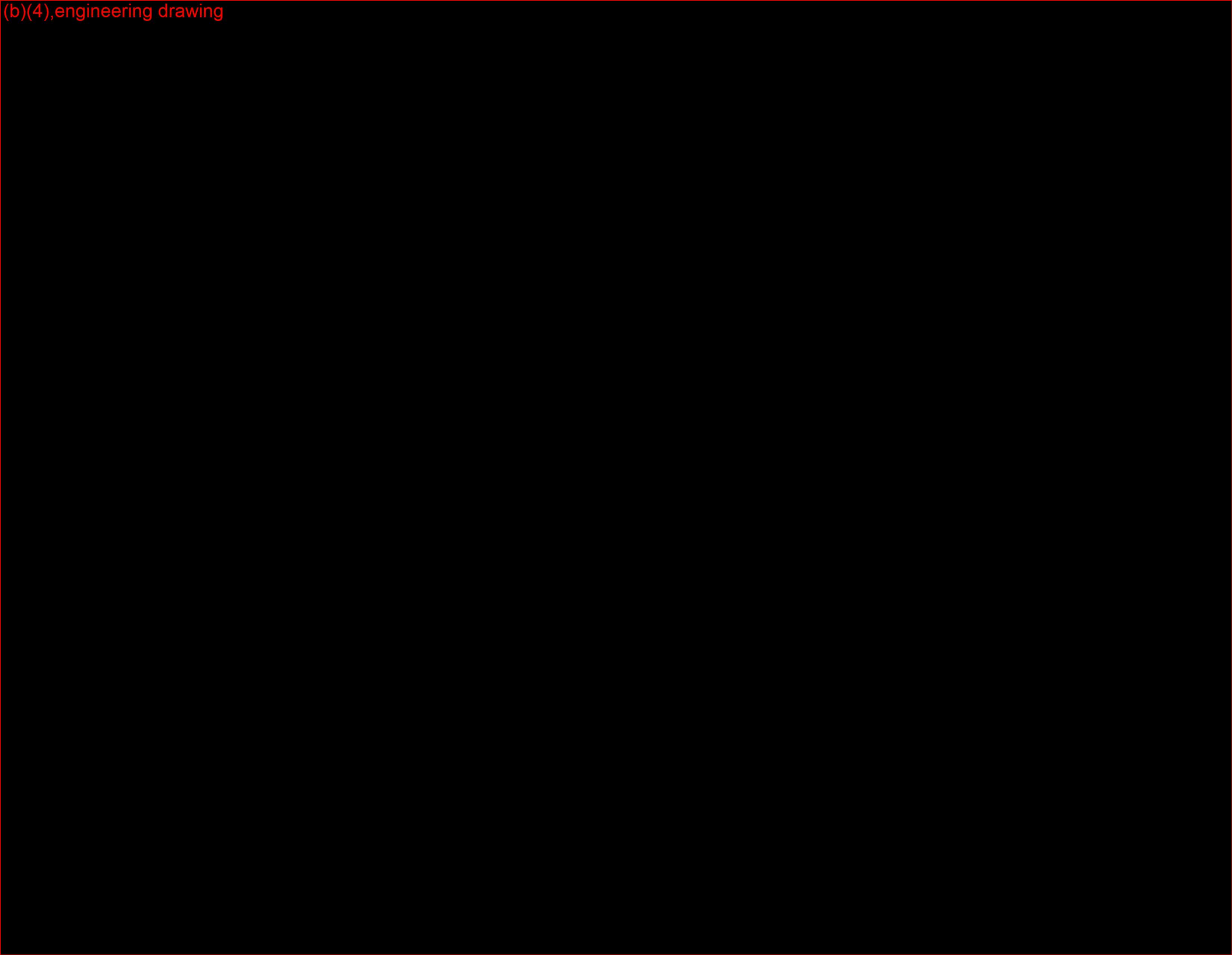
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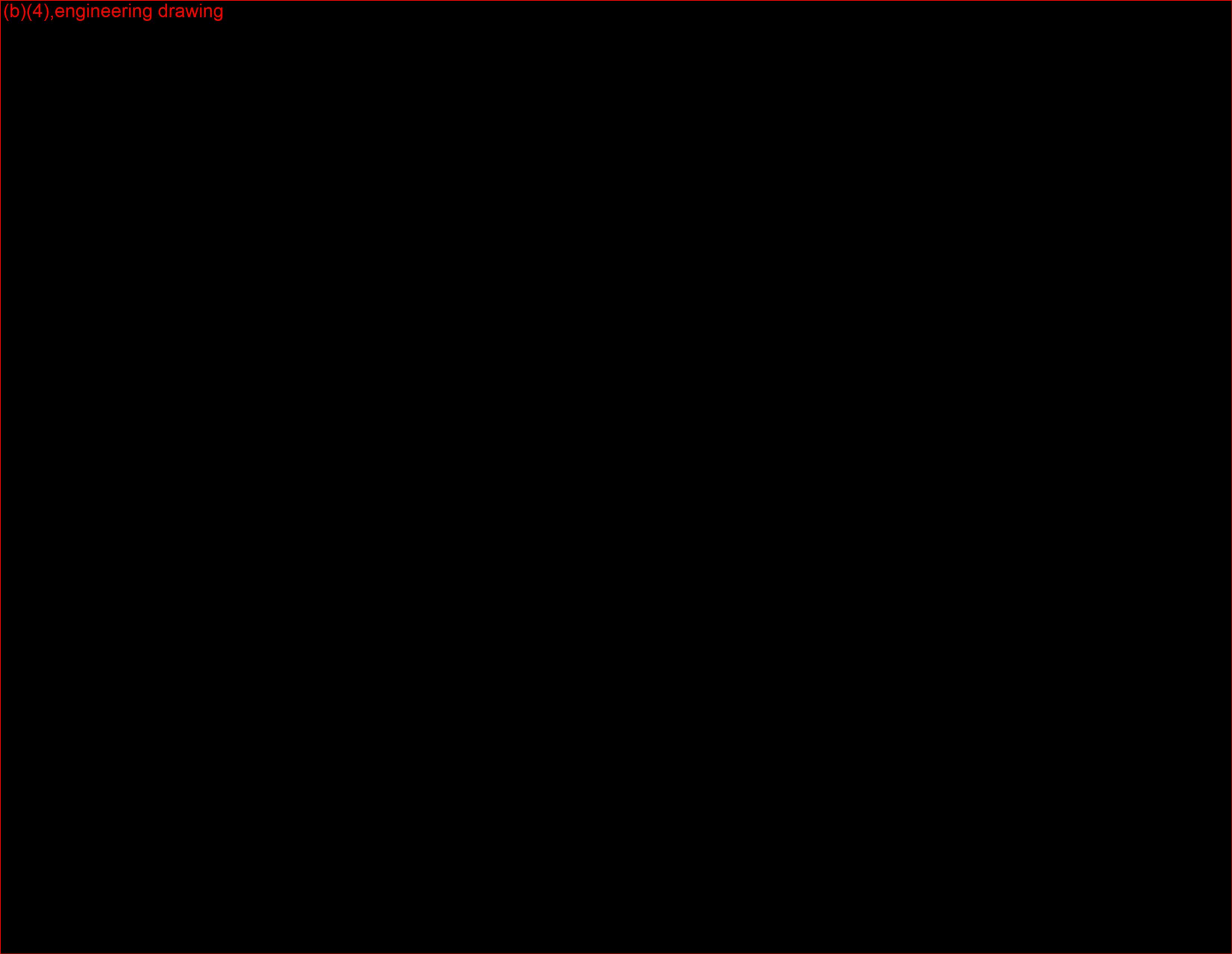
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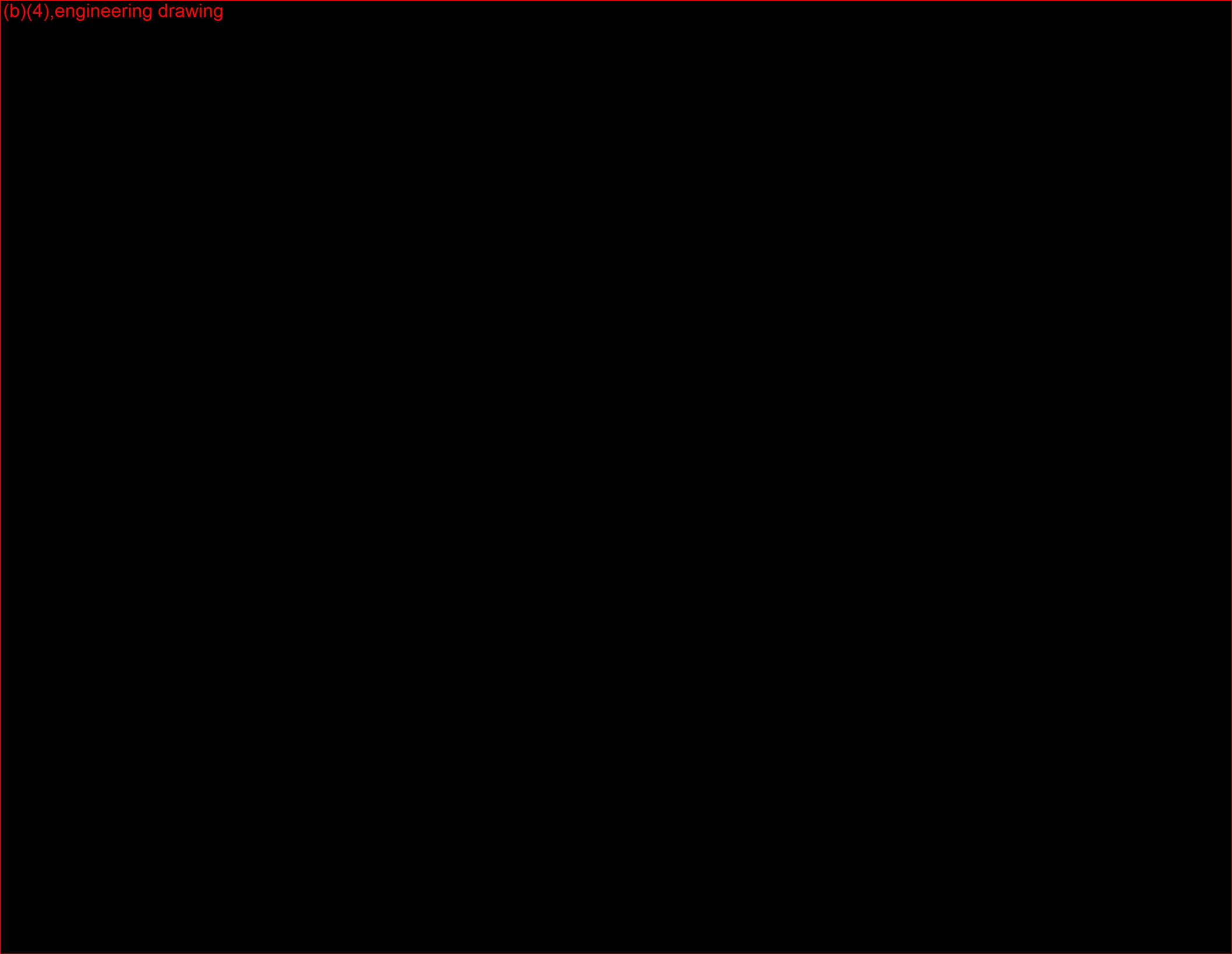
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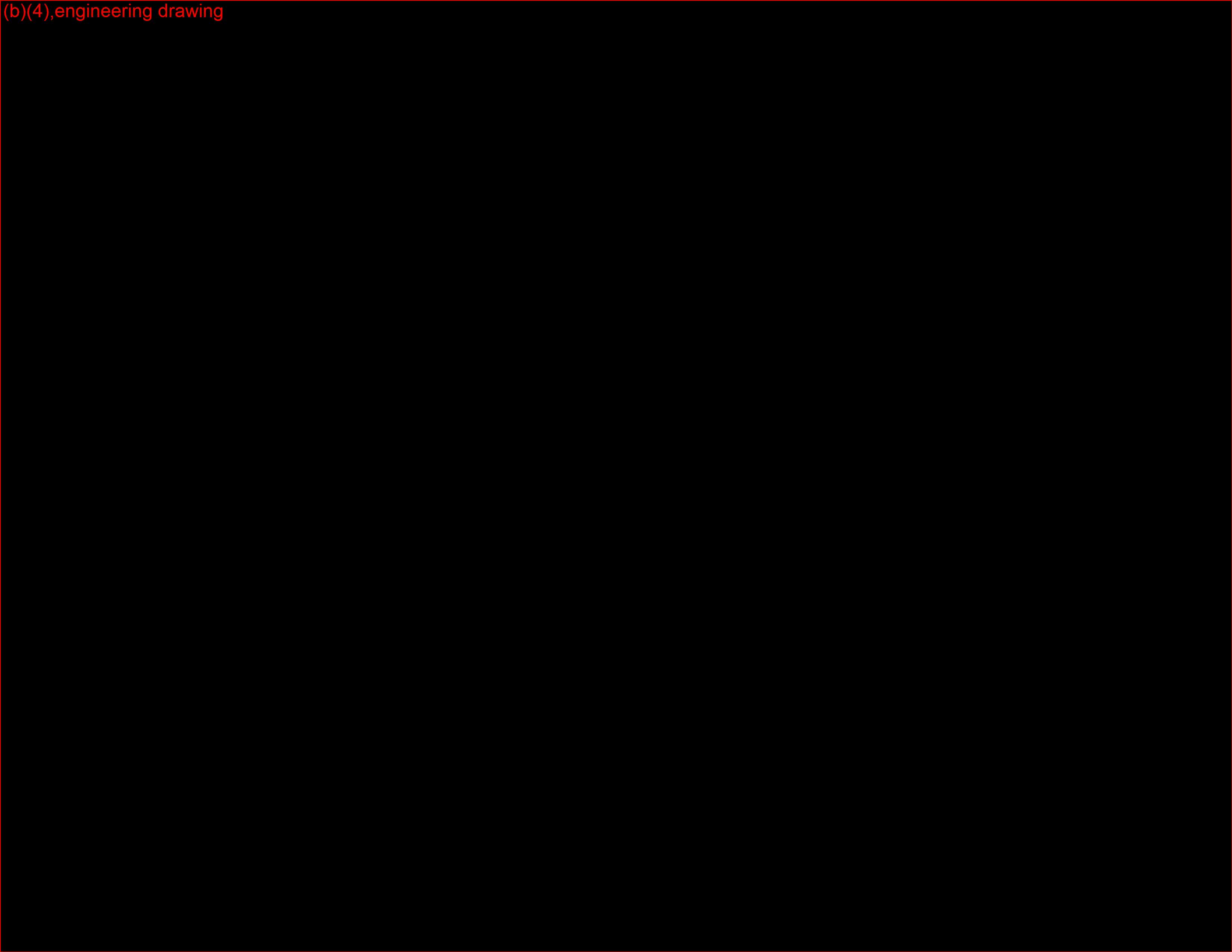
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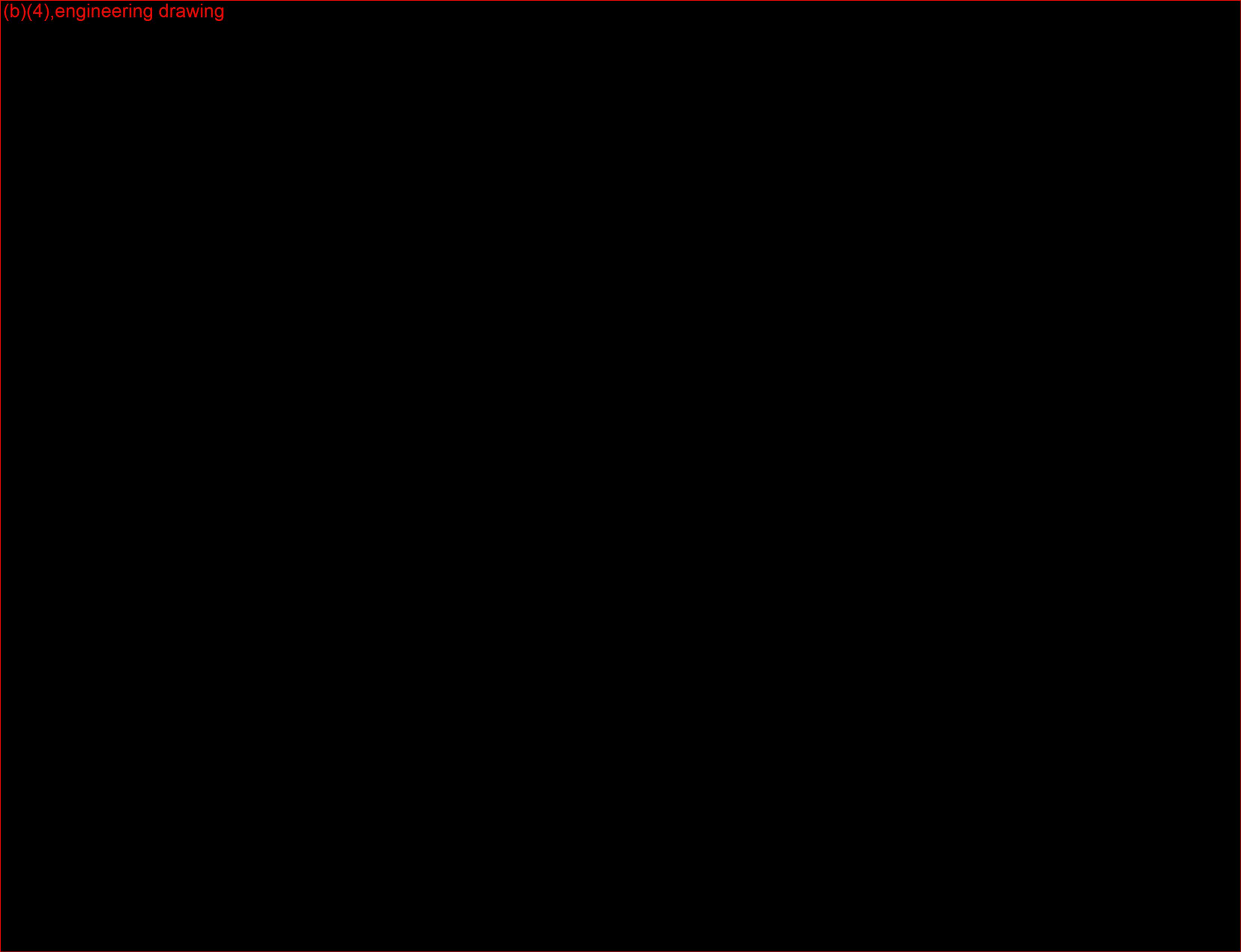
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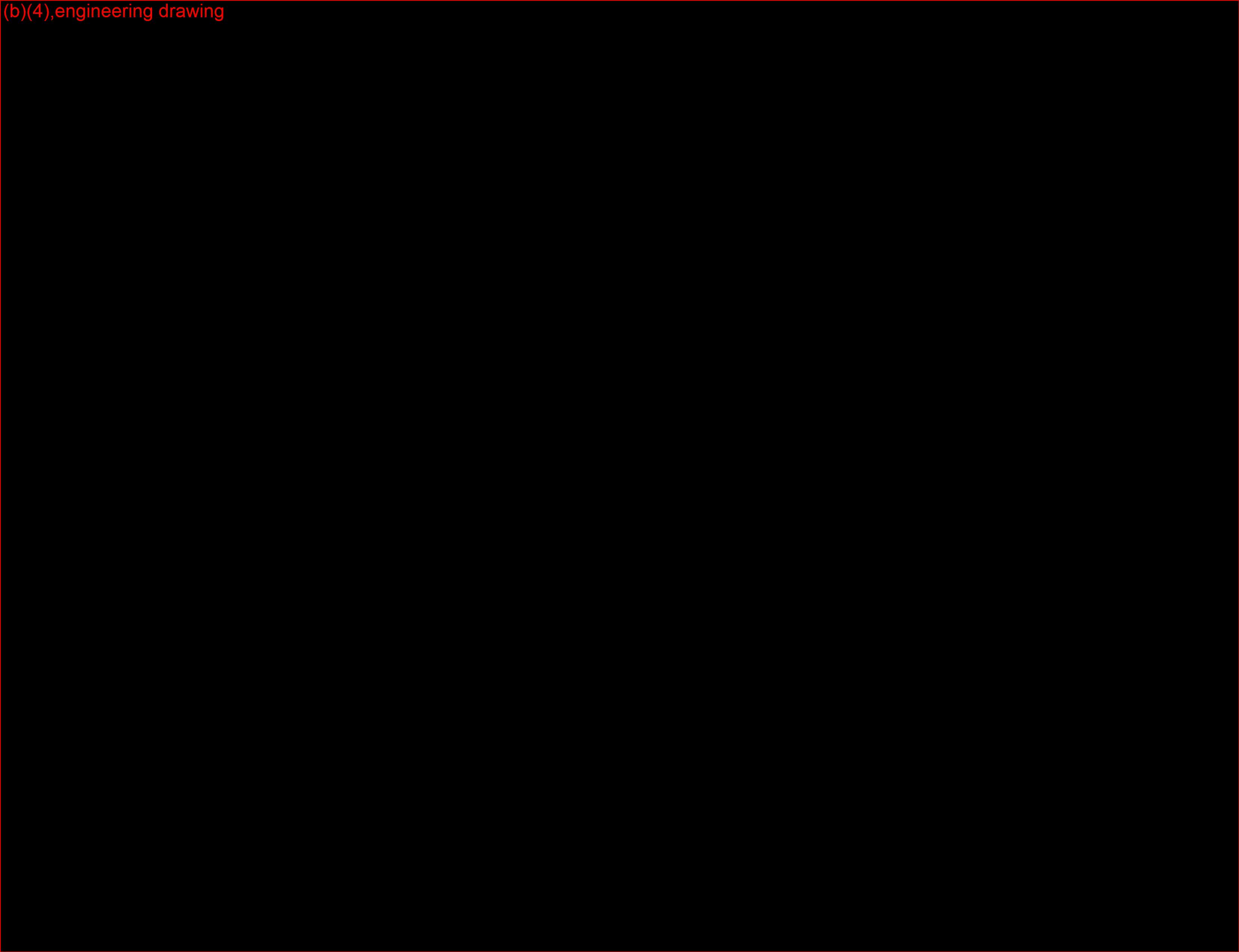
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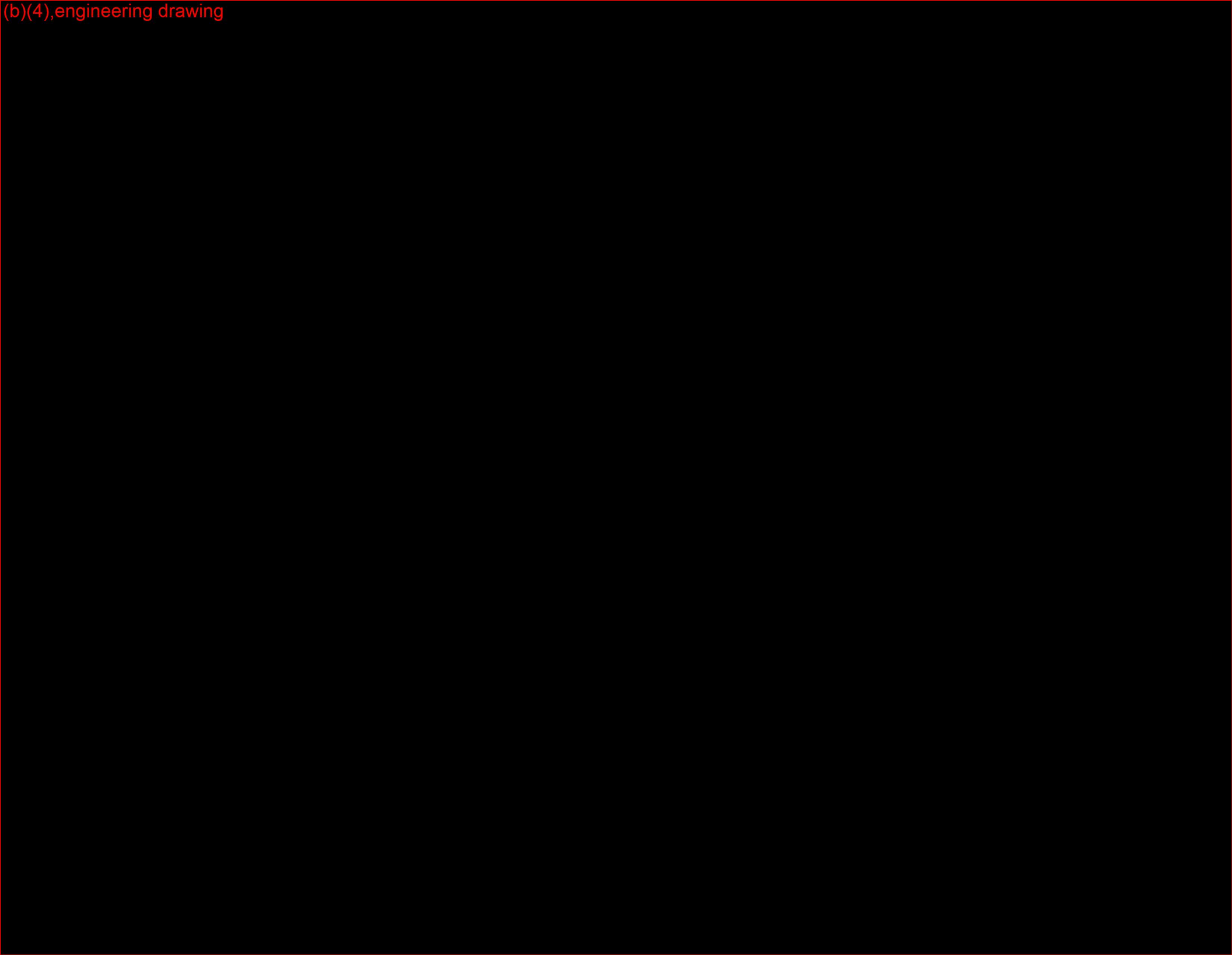
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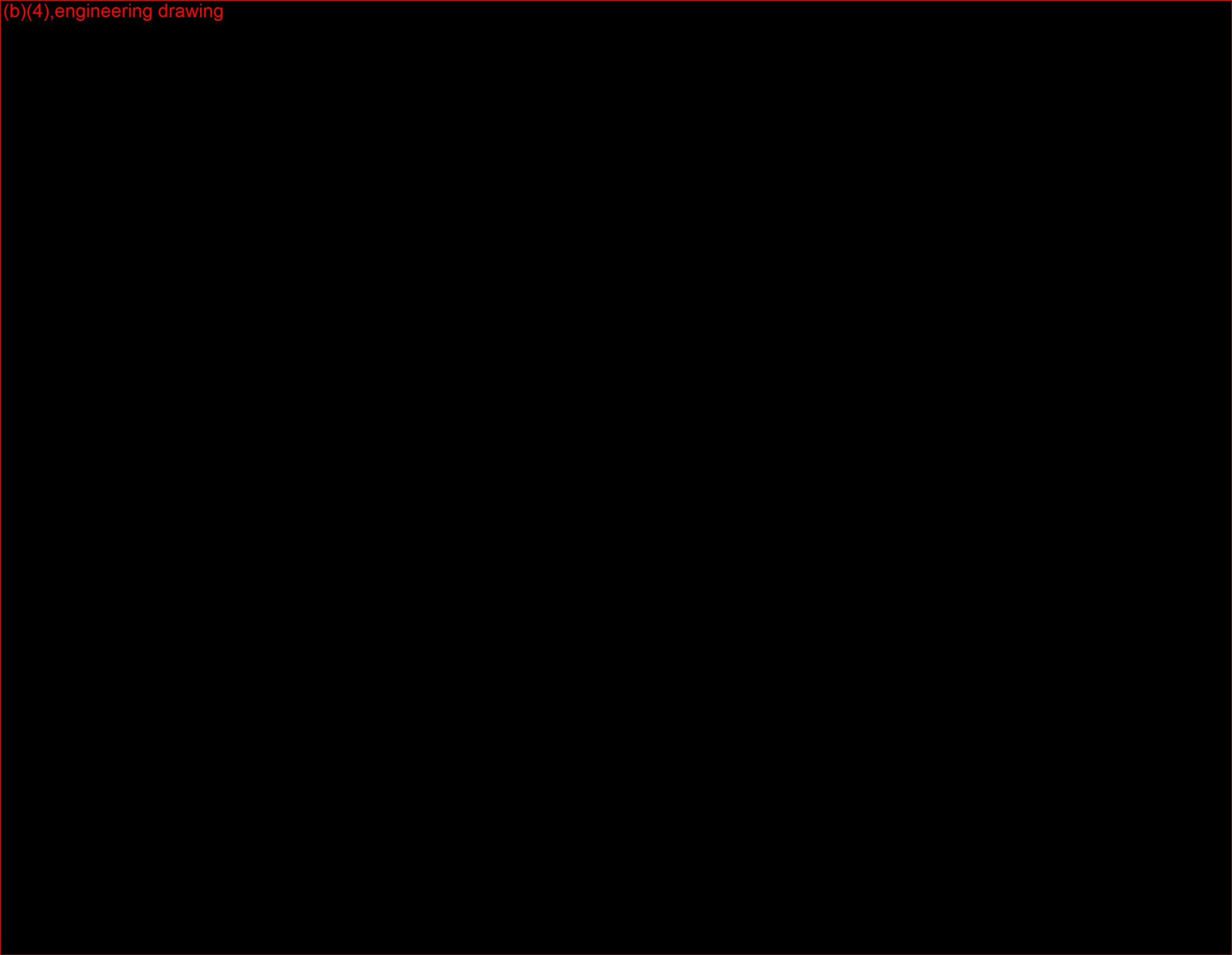
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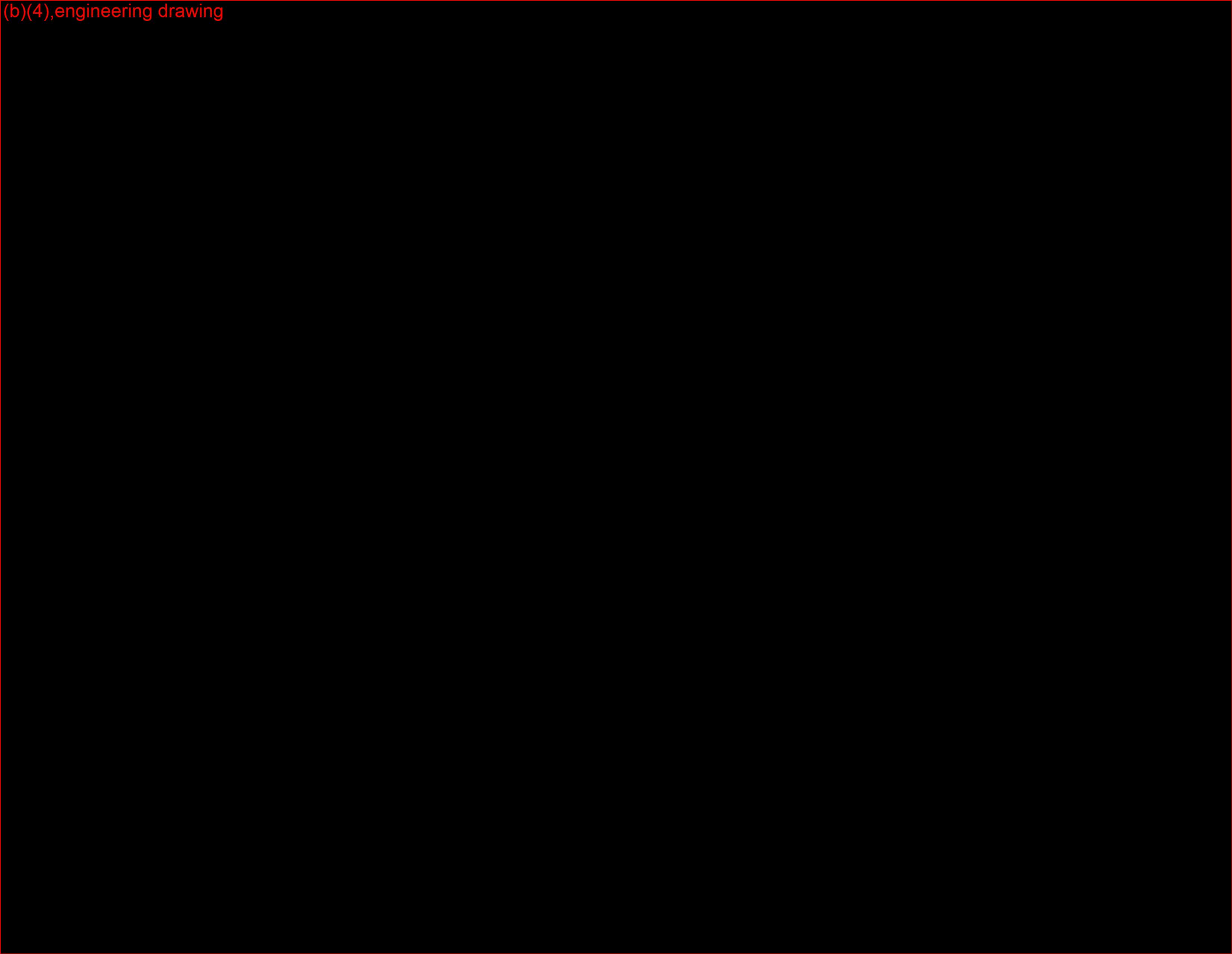
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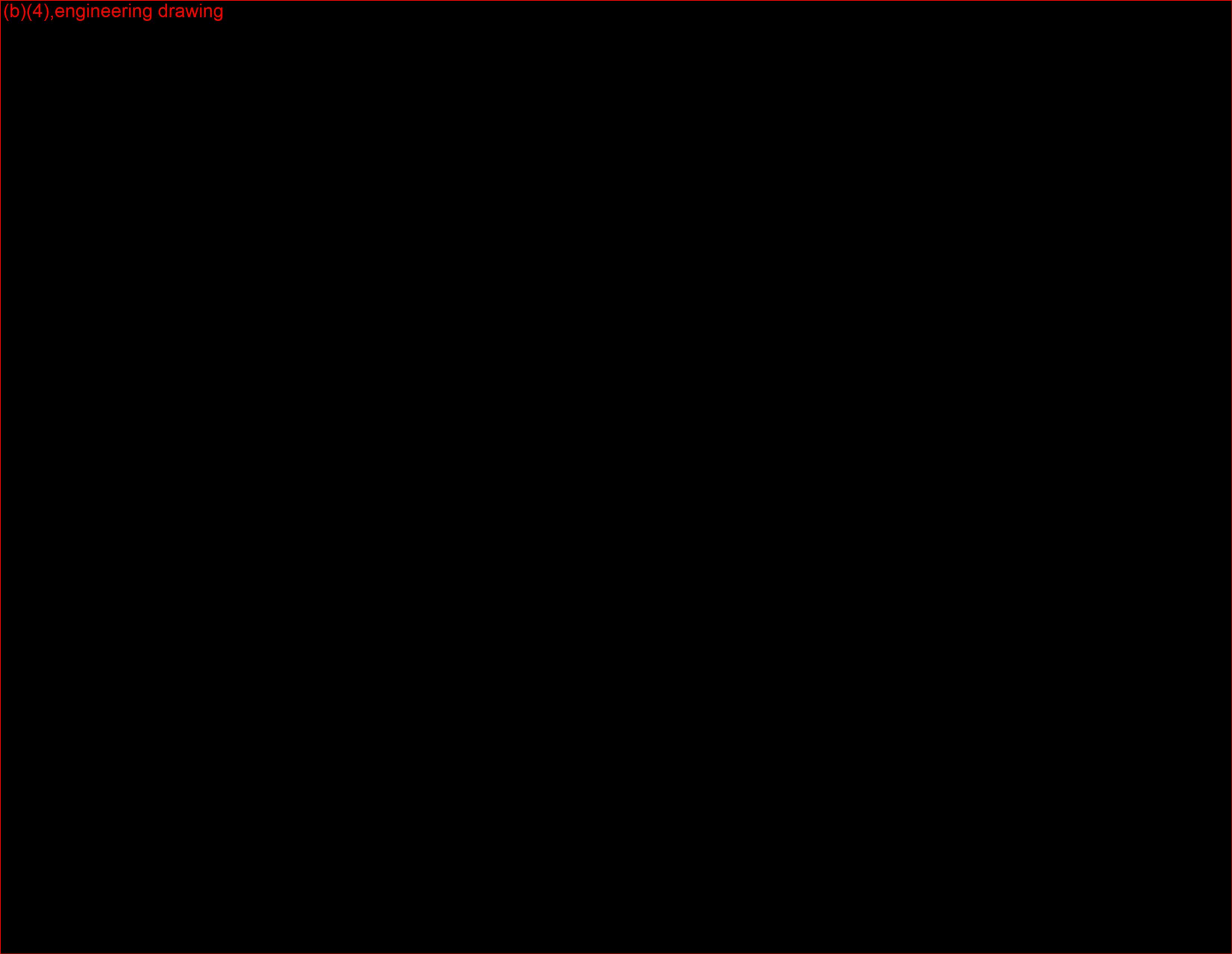
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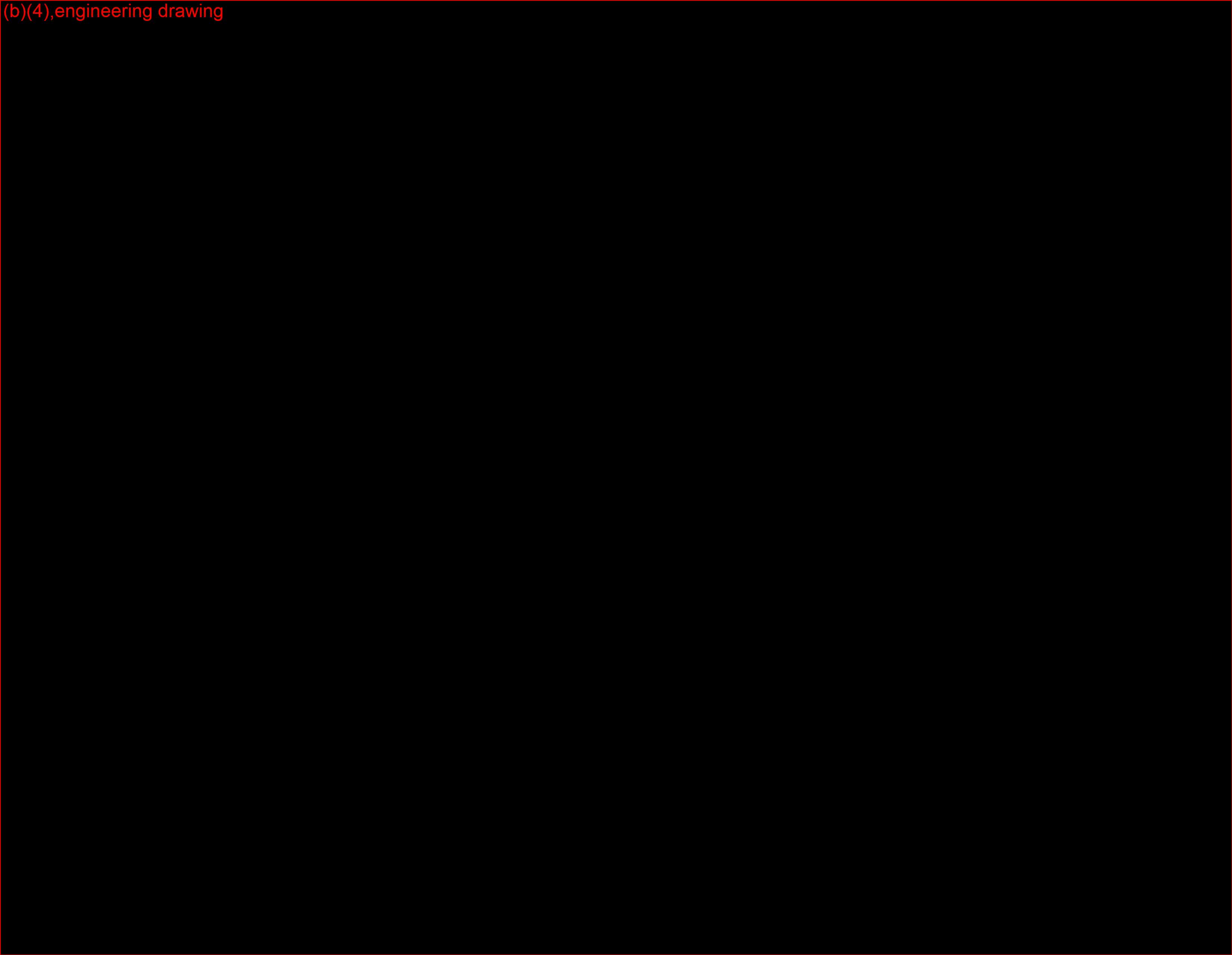
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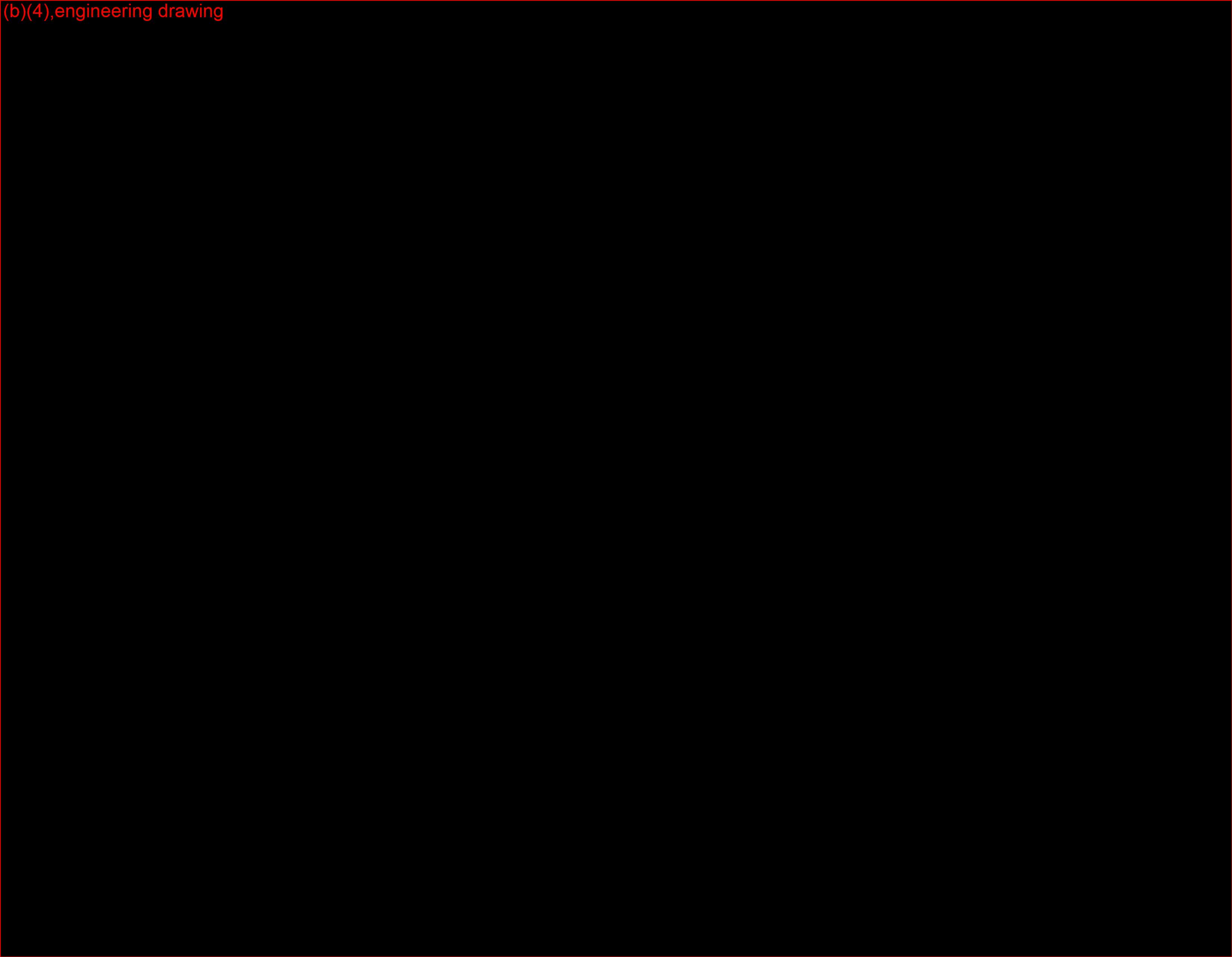
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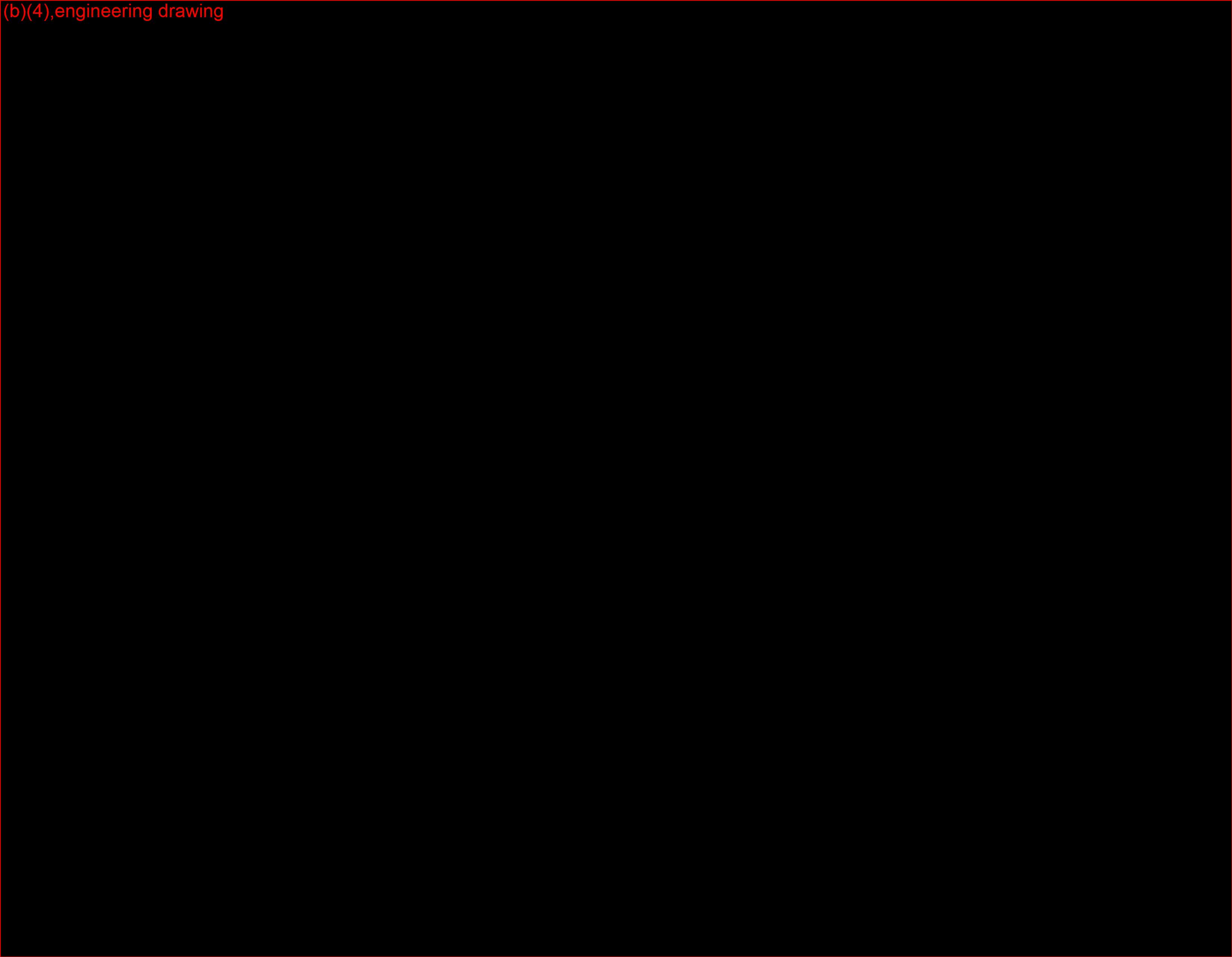
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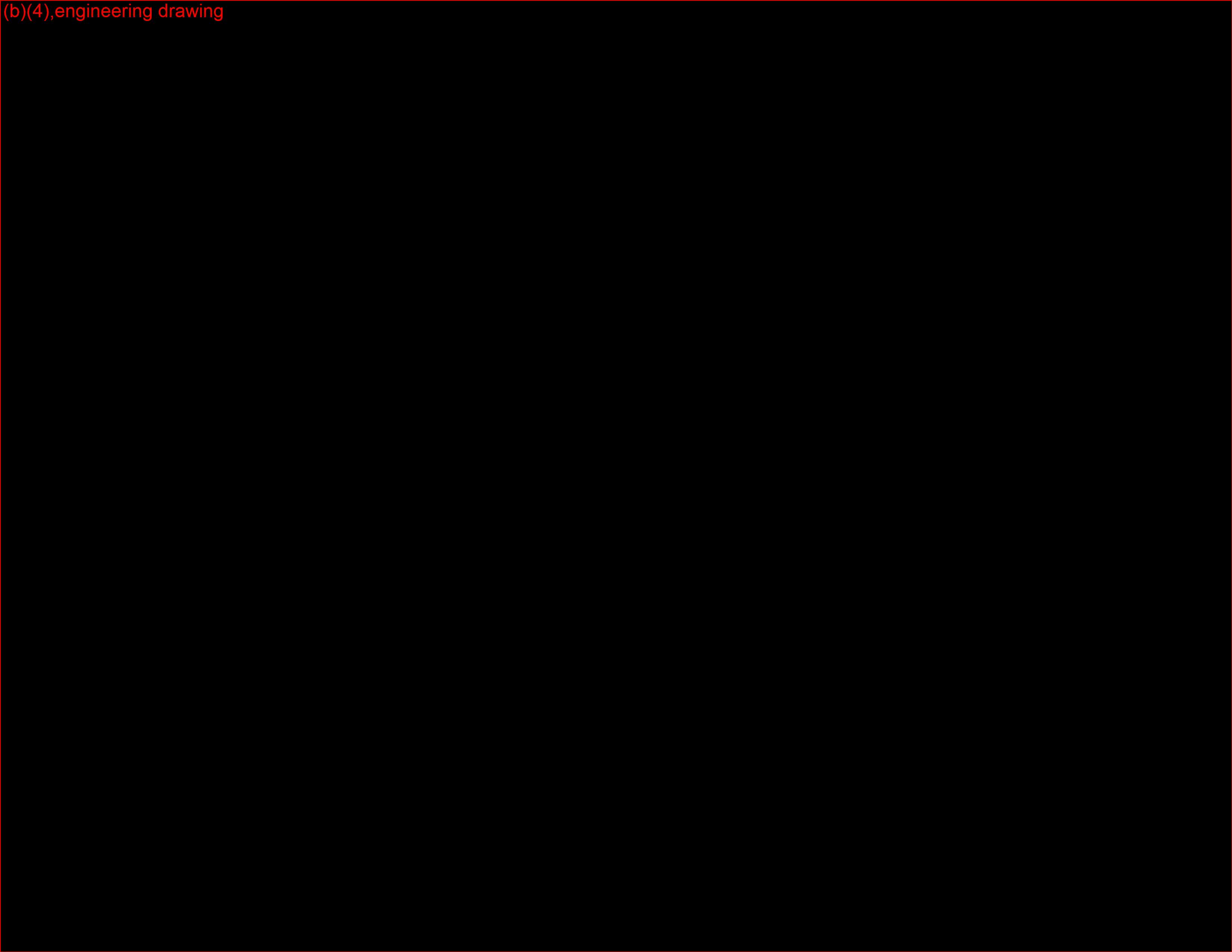
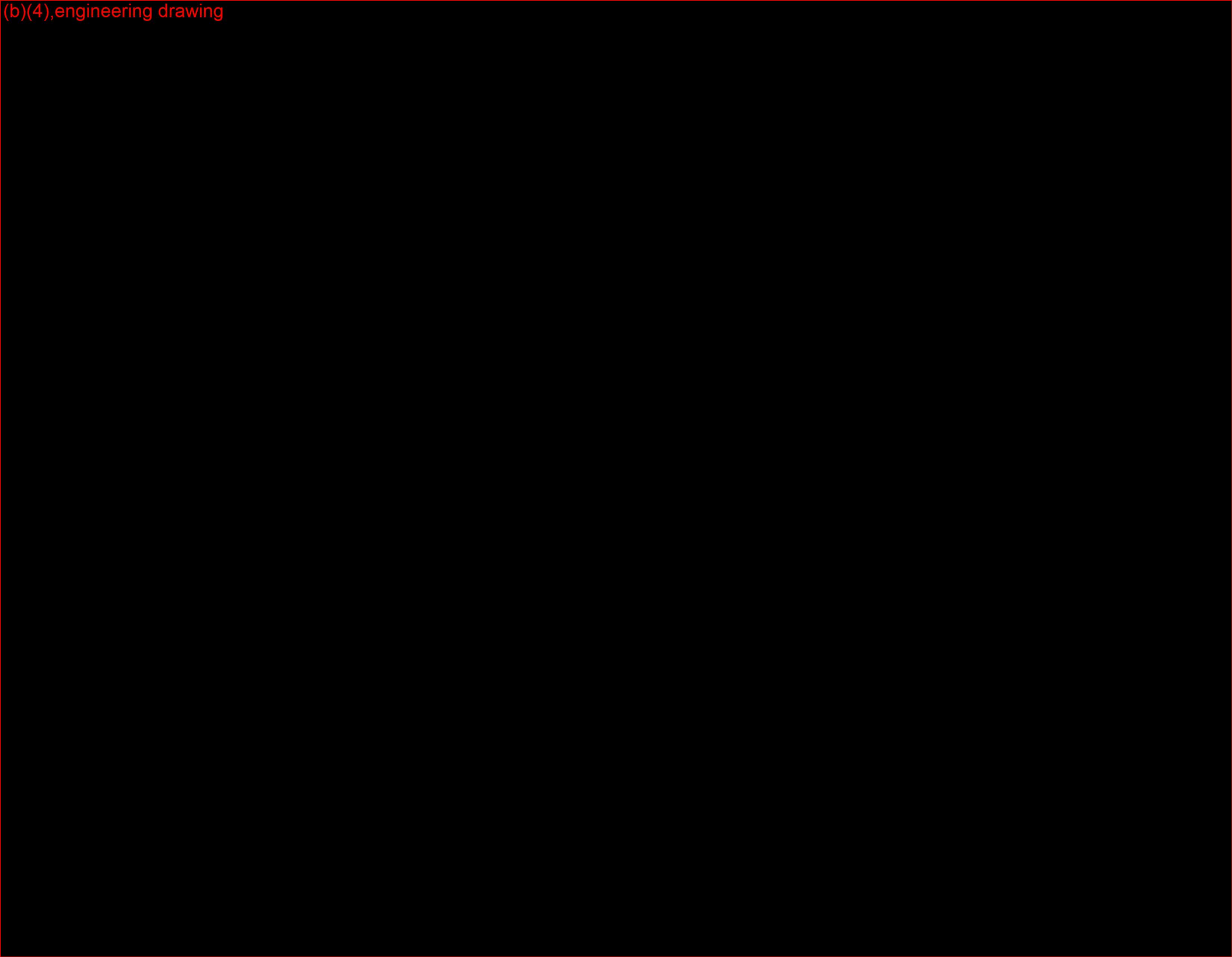

(b)(4),engineering drawing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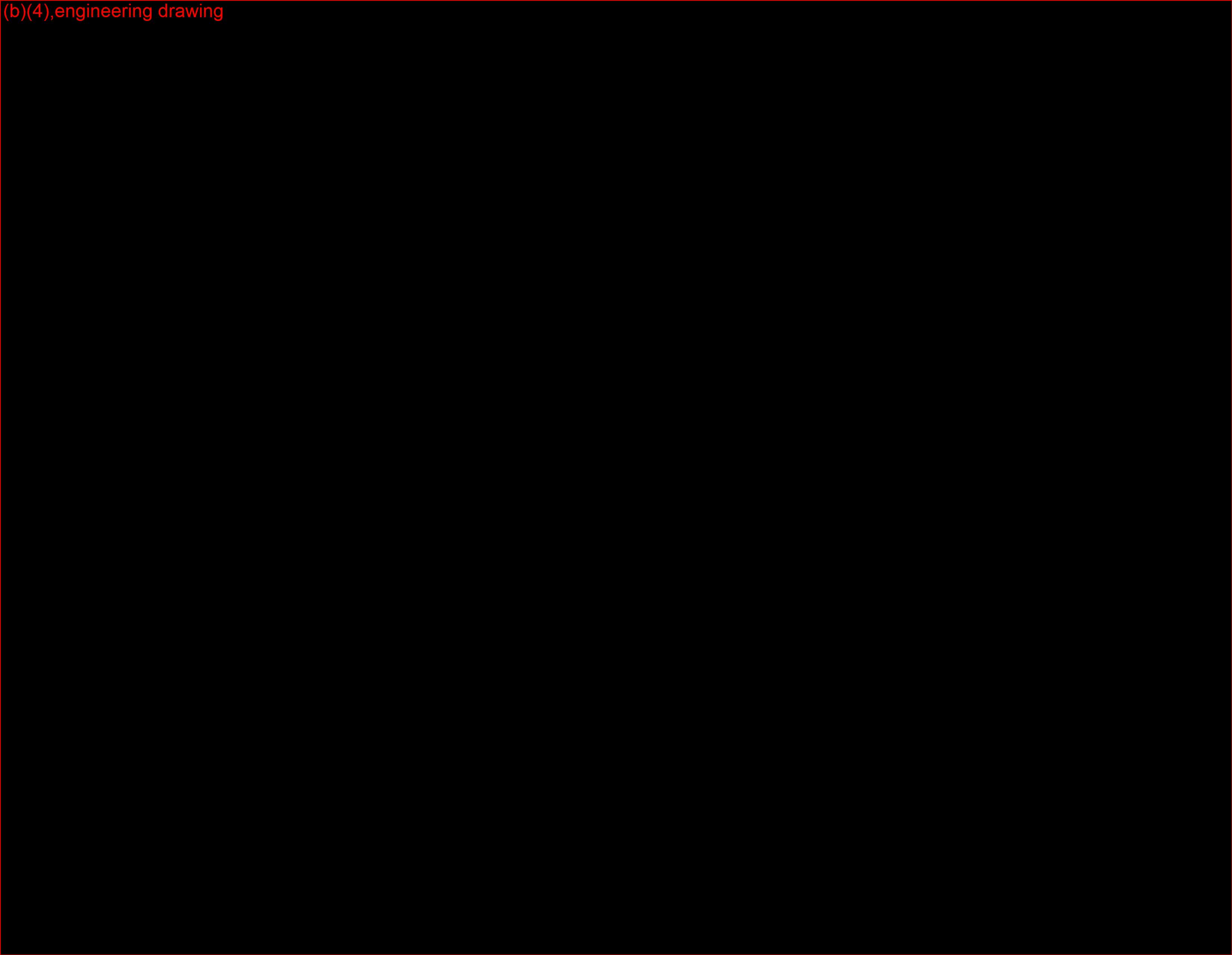
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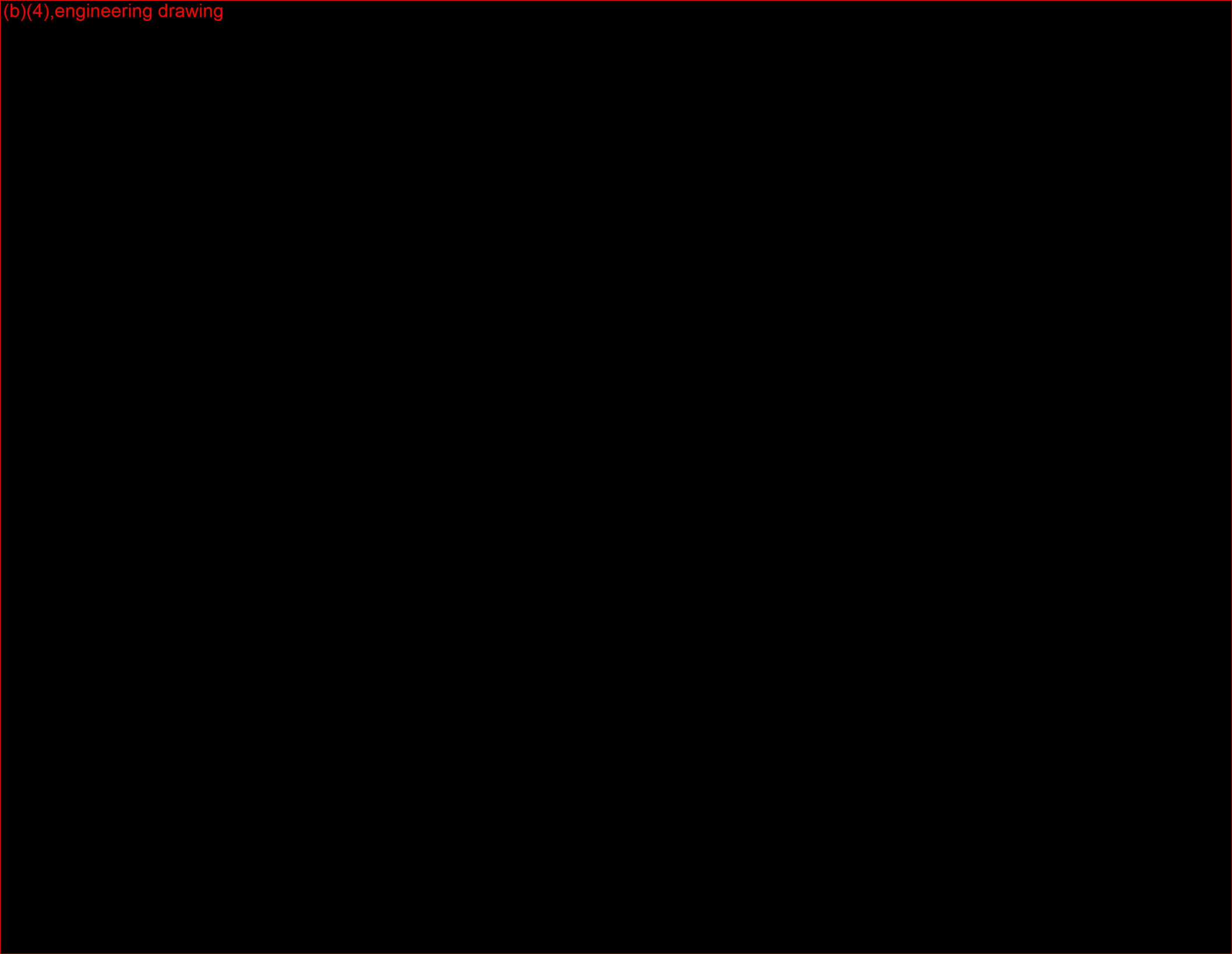
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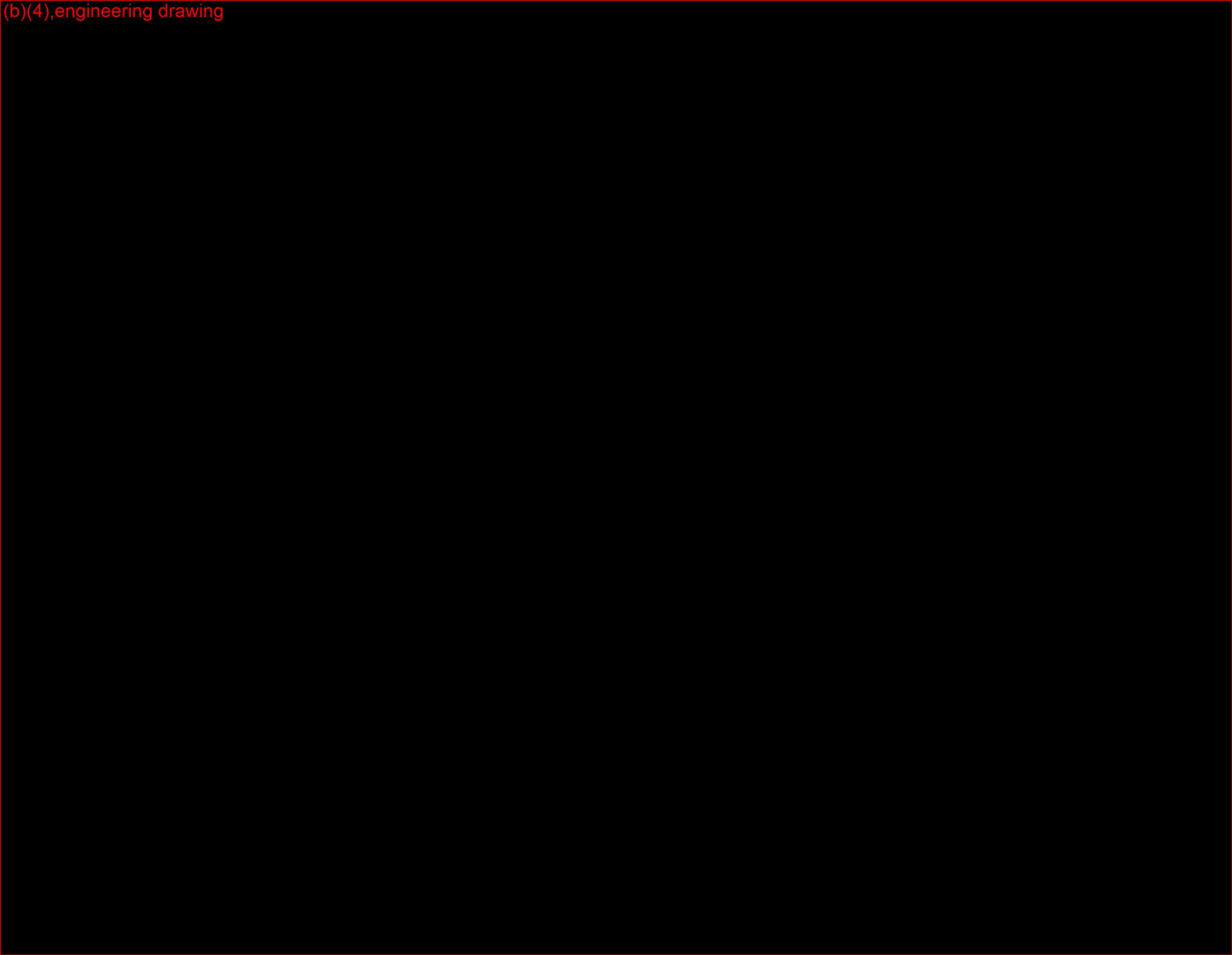
(b)(4),engineering drawing

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Predicate Device(s)

The predicate and design basis for the Zimmer Nexel Total Elbow (the proposed device) is the Coonrad/Morrey Total Elbow, manufactured by Zimmer. Clearance letters (K001989 and K053189 cleared 25 July 2000 and 9 December 2005, respectively) for the predicate device are included at the end of this section.

Similarities and differences between the proposed implants and the predicate implants are tabulated below.

Substantial Equivalence Comparison

Indications for Use

	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Intended Use	To be used in conjunction with bone cement to replace the articulating surfaces of the humeroulnar joint.	To be used in conjunction with bone cement to replace the articulating surfaces of the humeroulnar joint.
Indications for Use	• Elbow joint destruction which significantly compromises the activities of daily living • Post-traumatic lesions or bone loss contributing to elbow instability • Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis • Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain • Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis • Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus • Revision arthroplasty **CAUTION:** This device is intended for cemented use only.	• Elbow joint destruction which significantly compromises the activities of daily living • Post-traumatic lesions or bone loss contributing to elbow instability • Ankylosed joints, especially in cases of bilateral ankylosis from causes other than sepsis • Advanced rheumatoid or degenerative arthritis with incapacitating pain • Instability or loss of motion when the degree of joint damage precludes less radical procedures • Revision arthroplasty **CAUTION:** This device is intended for cemented use only.
Product Code	JDC	JDC

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Technology

	Feature	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Humeral Component – General	**Material**	Wrought Tivanium Alloy (Ti-6Al-4V) with Titanium Plasma Spray	Wrought Tivanium Alloy (Ti-6Al-4V) with a porous coating of Titanium Beads
	Fixation Method	Intended for cemented use only	Intended for cemented use only
	Comparable Sizes	Size 4, Standard Flange, 100mm →→→ Size 4, Standard Flange, 150mm →→→ Size 5, Standard Flange, 100mm →→→ Size 5, Standard Flange, 150mm →→→ Size 5, Long Flange, 150mm→→→→→ Size 5, Long Flange, 200mm→→→→→ Size 6, Standard Flange, 100mm →→→ Size 6, Standard Flange, 150mm →→→ Size 6, Long Flange, 150mm→→→→→ Size 6, Long Flange, 200mm→→→→→	→ Size Extra Small, Standard Flange, 4in → Size Extra Small, Standard Flange, 6in → Size Small, Standard Flange, 4in → Size Small, Standard Flange, 6in → Size Small, Long Flange, 6in → Size Small, Long Flange, 8in → Size Regular, Standard Flange, 4in → Size Regular, Standard Flange, 6in → Size Regular, Long Flange, 6in → Size Regular, Long Flange, 8in
	Sterility	Provided Sterile via Gamma Irradiation	Provided Sterile via Gamma Irradiation
	Design Features	• Humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal • Anterior flange designed to accept a bone graft and limit torsional and posterior migration • Humeral yoke with rounded corners to avoid the creation of stress risers within the medial and lateral humeral *supracondylar columns* • Plasma spray region to enhance fixation to bone cement within the medullary canal, and to improve fatigue strength • Features to accept Humeral Screws, Axle Pin and polymer Bearings A and B	• Humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal • Anterior flange designed to accept a bone graft and limit torsional and posterior migration • Humeral yoke with squared corners • Titanium Bead coating region to enhance fixation to bone cement within the medullary canal • Features to accept Axle Pin and polymer Bearings

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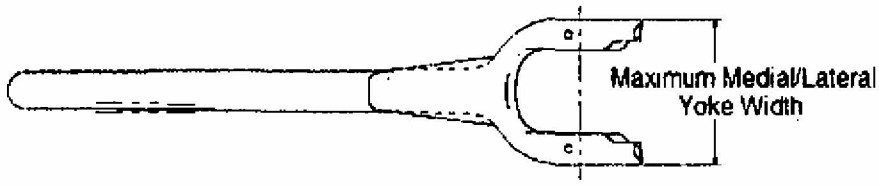
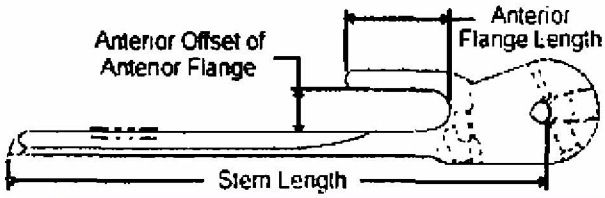
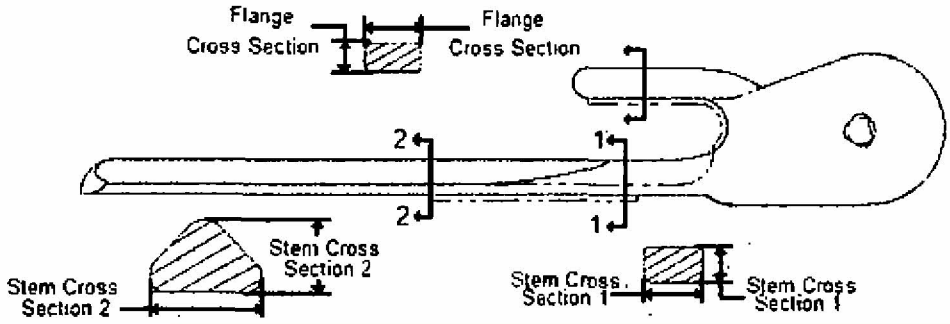
Humeral Component – Dimensional Comparison

Feature	Dimension	
	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
		
Max. M/L Yoke Width	(b)(4)	
		
Ant. Flange Offset	(b)(4)	
Flange Length		
Stem Length		
		
Flange Cross Section	(b)(4)	
Stem Cross Section 2 (distal region)		
Stem Cross Section 1 (plasma spray region)		

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	Feature	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Ulnar Component – General	**Material**	Wrought Tivanium Alloy (Ti-6Al-4V) with Titanium Plasma Spray	Wrought Tivanium Alloy (Ti-6Al-4V) with Titanium Plasma Spray
	Fixation Method	Intended for cemented use only	Intended for cemented use only
	Comparable Sizes	Left, Size 4, 75mm → Left, Size 4, 115mm → Left, Size 5, 75mm → Left, Size 5, 115mm → Left, Size 6, 90mm → Left, Size 6, 115mm → Right, Size 4, 75mm → Right, Size 4, 115mm → Right, Size 5, 75mm → Right, Size 5, 115mm → Right, Size 6, 90mm → Right, Size 6, 115mm →	→ Left, Size Extra Small, Standard → Left, Size Extra Small, Long → Left, Size Small, Standard → Left, Size Small, Long → Left, Size Regular, Standard → Left, Size Regular, Long → Right, Size Extra Small, Standard → Right, Size Extra Small, Long → Right, Size Small, Standard → Right, Size Small, Long → Right, Size Regular, Standard → Right, Size Regular, Long
	Sterility	Provided Sterile via Gamma Irradiation	Provided Sterile via Gamma Irradiation
	Design Features	• Left and right side-specific • Ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal • Ulnar eye that is both highly polished and nitrogen-enriched to limit wear of the apposing polymer bearings • Plasma spray region to enhance fixation to bone cement within the medullary canal	• Left and right side-specific • Ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal • Ulnar eye that is highly polished to limit wear of the apposing polymer bearings • Plasma spray region to enhance fixation to bone cement within the medullary canal

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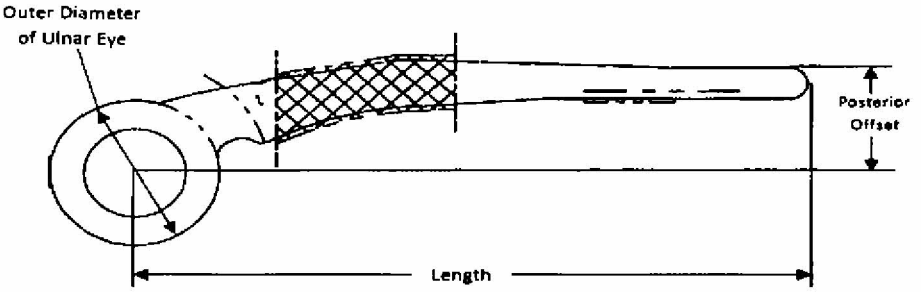
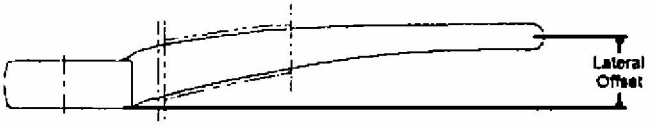
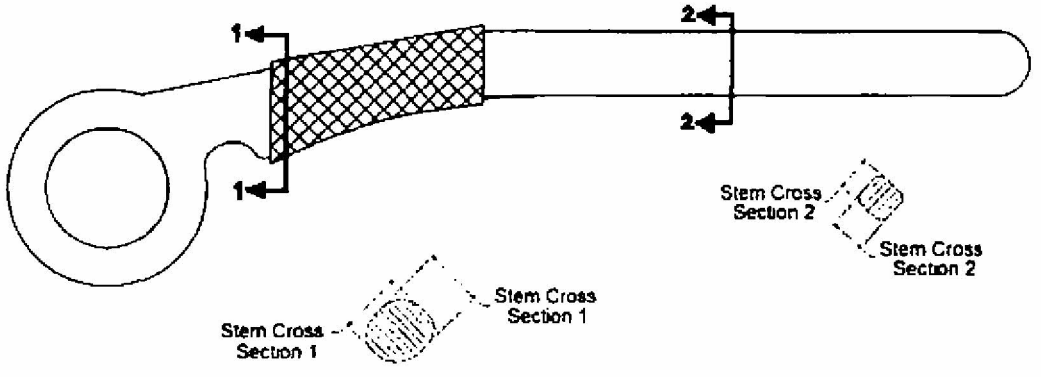
	Feature	Dimension: Proposed Device: The Zimmer Nexel Total Elbow	Dimension: Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Ulnar Component – Dimensional Comparison			
	OD of Ulnar Eye	(b)(4)	
	Posterior Offset		
	Stem Length		
			
	Lateral Offset	(b)(4)	
			
	Stem Cross Section 1 (plasma spray region)	(b)(4)	
	Stem Cross Section 2		

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	Feature	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Polyethylene Components - General	Material	Vitamin E HXPE (Vitamin E Highly Cross-Linked Polyethylene)	UHMWPE (Ultra-High Molecular-Weight Polyethylene)
	Fixation Method	Press-Fit to Humeral Component	Sliding-Fit to Humeral Component Press-Fit to Ulnar Component
	Sterility	Provided Sterile via Ethylene Oxide	Provided Sterile via Gamma Irradiation
	Design Features	• Bearings A and B: - Designed to broadly distribute joint reaction forces - Designed to articulate against the Eye of the Ulnar Component - Features to allow for press-fit mate to Humeral Component • Bearings B only: - Features to allow for press-fit mate to Axle Pin - Designed to articulate against the inner-diameter and the medial and lateral surfaces of the Eye of the Ulnar Component • Bearing A only: - Designed to articulate against the outer-diameter of the Eye of the Ulnar Component	• Humeral Bushings: - Designed to articulate with the medial and lateral sides of the Eye of the Ulnar Component - Features to allow for sliding-fit mate to the Humeral Component and sliding-fit mate to the Axle Pin (also known as Hinge Pin, also known as Snap Pin) • Ulnar Bushing: - Features to allow for a press-fit mate with the Eye of the Ulnar Component - Designed to articulate against the Humeral Bushings

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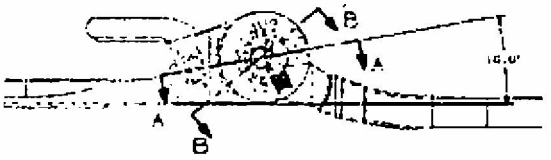
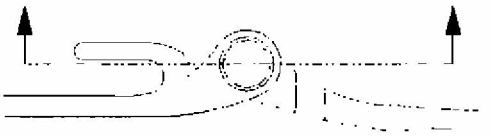
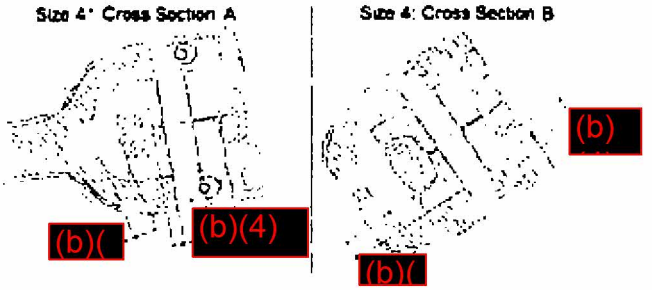
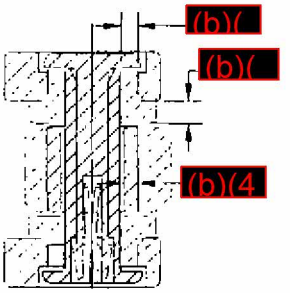
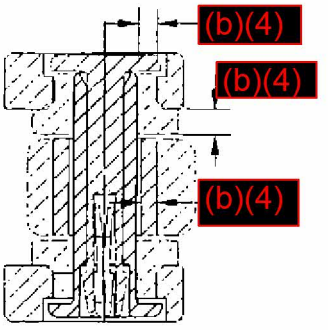
	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Polyethylene Components - Sizes		
		
	Size 4 • Maximum Thickness of Proximal/Distal • Articulating Surfaces: (b)(4 • Minimum Thickness of Proximal/Distal • Articulating Surfaces: (b)(• Maximum Thickness of Medial/Lateral • Articulating Surfaces: (b)(• Minimum Thickness of Medial/Lateral • Articulating Surfaces: (b)(	Size Extra Small • Maximum Thickness of Proximal/Distal Articulating Surfaces: (b)(• Minimum Thickness of Proximal/Distal Articulating Surfaces: (b)(" • Uniform Thickness of Medial/Lateral Articulating Surfaces (b)("
		
	Size 5/6 • Maximum Thickness of Proximal/Distal • Articulating Surfaces: (b)(4 • Minimum Thickness of Proximal/Distal • Articulating Surfaces: (b)(• Maximum Thickness of Medial/Lateral • Articulating Surfaces: (b)(4 • Minimum Thickness of Medial/Lateral • Articulating Surfaces: (b)(4	Size Small / Regular • Maximum Thickness of Proximal/Distal Articulating Surfaces (b)(4 • Minimum Thickness of Proximal/Distal Articulating Surfaces (b)(4 • Uniform Thickness of Medial/Lateral Articulating Surfaces: (b)(4

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	Feature	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Axle Pin	Material	Zimaloy (Cobalt-Chromium-Molybdenum Alloy)	Zimaloy (Cobalt-Chromium-Molybdenum Alloy)
	Fixation Method	• Press-Fit to Bearings B • Compression fit between the taper of the Humeral Screws and the yoke of the Humeral Component	• Sliding-Fit to Bearings • Snap-Fit between inner and outer Axle Pin components
	Sizes	Size 4 (b)(4) Long Diameter • Solid Material Throughout Size 5/6 (b)(4) Long Diameter • Solid Material Throughout	Size Extra Small (b)(4) Long Outer Diameter Wall Thickness Size Small/Regular (b)(4) Long Outer Diameter Wall Thickness
	Sterility	Provided Sterile via Ethylene Oxide	Provided Sterile via Gamma Irradiation
	Design Features	• Designed to remain in a fixed position (not translate nor rotate) throughout the entire humeroulnar joint range of motion • Machined complete as a single, solid component	• Designed to freely rotate and slide • Machined as 2 (an inner and an outer) hollow components that snap together intraoperatively
Humeral Screws	Material	Zimaloy (Cobalt-Chromium-Molybdenum Alloy)	Not Applicable: No comparable part in the predicate system
	Fixation Method	Threads engage with the Spiralock® threads of the Humeral Component	
	Sizes	Single size mates with all humeral component sizes and both axle pin sizes	
	Sterility	Provided Sterile via Gamma Irradiation	
	Design Features	• Designed to remain in a fixed position throughout the entire humeroulnar joint range of motion (not directly loaded by any compressive joint reaction force during flexion or extension of the humeroulnar joint) • Headless design intended to ensure the constant application of a clamp-load to the axle-pin and to avoid soft tissue impingement or irritation associated with a protruding screw head • Non-threaded taper to (along with the Humeral Component) hold Axle Pin in compression • Pilot feature to avoid cross-threading	

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	Semi-Constraint Characteristics		Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Semi-Constrained Range of Motion (defined in terms of Ulnar Component movement with respect to Humeral Component)	Varus/Valgus Angular Laxity		Neutral to Maximum Varus: (b)(4) Neutral to Maximum Valgus: (b)(4) Total Included Angle: (b)(4)	Neutral to Maximum Varus: (b)(4) Neutral to Maximum Valgus: (b)(4) Total Included Angle: (b)(4)
	Internal/External Rotational Laxity		Neutral to Maximum Internal Rotation: (b)(4) Neutral to Maximum External Rotation: (b)(4) Total Included Angle: (b)(4)	Neutral to Maximum Internal Rotation: (b)(4) Neutral to Maximum External Rotation: (b)(4) Total Included Angle: (b)(4)
	Pistoning	Proximal/Distal Translational Laxity	Neutral to Maximum Proximal: (b)(4) Neutral to Maximum Distal: Total Proximal/Distal Laxity:	Neutral to Maximum Proximal: (b)(4) Neutral to Maximum Distal: Total Proximal/Distal Laxity:
		Anterior/Posterior Translation Laxity	Neutral to Maximum Anterior: Neutral to Maximum Posterior: Total Anterior/Posterior Laxity:	Neutral to Maximum Anterior: Neutral to Maximum Posterior: Total Anterior/Posterior Laxity:
	Medial/Lateral Translation Laxity		Neutral to Maximum Medial: Neutral to Maximum Lateral: Total Medial/Lateral Laxity:	Neutral to Maximum Medial: Neutral to Maximum Lateral: Total Medial/Lateral Laxity:
	Flexion/Extension Range (defined in terms of degrees flexion)		All Humeral and Ulnar combinations: (b)(4)	Humeral size XS with Ulnar size XS: (b)(4) Humeral size XS with Ulnar size S: (b)(4) Humeral size XS with Ulnar size REG: (b)(4) Humeral size S with Ulnar size XS: (b)(4) Humeral size S with Ulnar size S: (b)(4) Humeral size S with Ulnar size REG: (b)(4) Humeral size REG with Ulnar size XS: (b)(4) Humeral size REG with Ulnar size S: (b)(4) Humeral size REG with Ulnar size REG: (b)(4)

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Performance Specifications

Test	Test Results	
	Proposed Device: The Zimmer Nexel Total Elbow	Predicate Device: The Coonrad/Morrey Total Elbow (K001918, K053189)
Fatigue Testing: Humeral Stem (Plasma Spray Region)	Five Zimmer Nexel Total Elbow humeral stems achieved (b)(4) load cycles at (b)(without fracture.	The predicate device humeral component was fatigue tested at various load levels, and the fatigue strength at (b)(4) cycles was determined to be (b)(
Fatigue Testing: Ulnar Stem (Mid-Stem Region)	Five Zimmer Nexel Total Elbow ulnar stems achieved (b)(4) load cycles in the mid-stem region at a load of (b)(without fracture.	The predicate device ulnar component was fatigue tested at various load levels, and the fatigue strength a(b)(4) load cycles in the mid-stem region was determined to be (b)(
Fatigue Testing: Ulnar Stem (Plasma Spray Region)	Five Zimmer Nexel Total Elbow ulnar stems achieved (b)(4) load cycles in the plasma spray region at a load of (b)(without fracture.	The predicate device ulnar component was fatigue tested at various load levels, and the fatigue strength at (b)(4) oad cycles in the plasma spray region was determined to be(b)(
Wear Testing	The Zimmer Nexel Total Elbow mean gravimetric wear rate (b)(4) at (b)(4) load cycles) was (b) less than that of the predicate.	The predicate device mean gravimetric wear rate was(b)(4) load cycles.
Durability Testing	The Zimmer Nexel Total Elbow device achieved (b)(4) run-outs at an equivalent of (b)(weight-in-hand.	The run out load for the predicate device was found to be equivalent to(b)(4) weight-in-hand.
Modular Connection Fatigue Testing	The median fatigue strength of the non-articulating, mechanically locked, modular Zimmer Nexel Total Elbow implant components was no less than (b)(4)	Not Applicable: The Zimmer Coonrad/Morrey Total Elbow does not have non-articulating, mechanically-locked, modular implant components comparable to those of the proposed device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

C-000412

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2000

Ms. Laura D. Williams
Regulatory Affairs Associate
Zimmer
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K001989
Trade Name: Coonrad/Morrey Total Elbow
Regulatory Class: II
Product Code: JDC
Dated: June 28, 2000
Received: June 29, 2000

Dear Ms. Williams:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Exhibit B

510(k) Number (if known) K001989

Device Name:

Coonrad/Morrey Total Elbow

Indications for Use:

Indications include: post-traumatic lesions or bone loss contributing to elbow instability; ankylosed joints, especially in cases of bilateral ankylosis from causes other than sepsis; advanced rheumatoid or degenerative arthritis with incapacitating pain; revision arthroplasty, and instability or loss of motion when the degree of joint damage precludes less radical procedures.

The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises the activities of daily living. Patients with single joint involvement (generally those with traumatic or degenerative arthritis) or significant lower extremity disability which require walking aids are less amenable to treatment than patients with advanced and predominately upper extremity involvement. If possible, elbow replacement should be done after hip or knee surgery to avoid excessive stress to the prosthesis required by crutch walking during total hip or knee rehabilitation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

RA06004K.510

Donna R. Vuchnes.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001989

23

Records processed under FOIA request #2016-4653; Released by CDRH on 07/26/2017

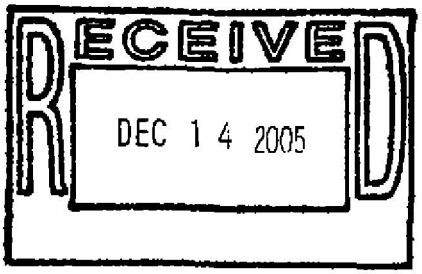
K053189

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005



Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K053189
Trade/Device Name: Coonrad/Morrey Total Elbow
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: JDC
Dated: November 11, 2005
Received: November 15, 2005

Dear Ms. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

K053189

Indications for Use

510(k) Number (if known):

Device Name:

Coonrad/Morrey Total Elbow

Indications for Use:

Indications include: post-traumatic lesions or bone loss contributing to elbow instability; ankylosed joints, especially in cases of bilateral ankylosis from causes other than sepsis; advanced rheumatoid or degenerative arthritis with incapacitating pain; revision arthroplasty, and instability or loss of motion when the degree of joint damage precludes less radical procedures.

The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises the activities of daily living. Patient with single joint involvement (generally those with traumatic or degenerative arthritis) or significant lower extremity disability which require walking aids are less amenable to treatment than patients with advanced and predominantly upper extremity involvement. If possible, elbow replacement should be done after hip or knee surgery to avoid excessive stress to the prosthesis required by crutch walking during total hip or knee rehabilitation.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053189

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Labeling

Draft labels for each of the proposed components are presented below, along with the draft package insert and draft surgical technique.

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Product Photo

REF Reference Number 00-8400-014-07

Zimmer® Nexel™ Total Elbow

Ulnar Component Plasma Sprayed

Size 4 75 mm Length Left

Use By 2019-09

Human Readable

For Cemented Use Only

LOT Lot Number 99999999

EDI: 00840001407

Zimmer® Nexel™ Total Elbow

Ulnar Component Plasma Sprayed

Size 4 75 mm Length Left

Tivanium® Ti-6Al-4V Alloy Sterile Qty-1

℞ only

REF Reference Number 00-8400-014-07

Manufactured

Zimmer® WARSAW, IN 46580 U.S.A.

Lot No.

Item Number: H_ProductID

Description: H_ProductionDescnpt

Operation: H_Operation

Date of Issue: H_ProductionPackAppr

Sterility: H_Sterilitytype

Prod Pack Version: H_ProductionPackVers

Prod Pack Ver Date: H_ProductionPackDesi

Qty\Pkg: H_QuantityPerPackage

131

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Product Photo

REF Reference Number 00-8400-044-10
Zimmer® Nexel™ Total Elbow
Humeral Component Plasma Sprayed
Size 4 100 mm Length

Use By 2019-09

Human Readable

For Cemented Use Only

LOT Lot Number 99999999 **EDI: 00840004410**
Zimmer® Nexel™ Total Elbow
Humeral Component Plasma Sprayed
Size 4 100 mm Length
Tivanium® Ti-6Al-4V Alloy Sterile Qty-1

Rx only

REF Reference Number 00-8400-044-10

Manufacturer
ZIMMER® WARSAW, IN 46580 U.S.A.

LOT No.

Item Number: H_ProductID
Description: H_ProductionDescrpt
Operation: H_Operation
Date of Issue: H_ProductionPackAppr
Sterility: H_Sterilitytype
Prod Pack Version: H_ProductionPackVers
Prod Pack Ver Date: H_ProductionPackDesi
Qty\Pkg: H_QuantityPerPackage

132

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Product Photo

REF Reference Number 00-8400-055-15

Zimmer® Nexel™ Total Elbow

Humeral Component Plasma Sprayed

Size 5 150 mm Length Long Flange

For Cemented Use Only

Use by 2019-09

Human Readable

LOT Lot Number 99999999

EDI: 00840005515

Zimmer® Nexel™ Total Elbow

Humeral Component Plasma Sprayed

Size 5 150 mm Length Long Flange

Tivanium® Ti-6Al-4V Alloy Sterile Qty-1

℞ only

REF Reference Number 00-8400-055-15

Manufacturer

ZIMMER WARSAW IN 46580 U.S.A.

LOT No.

Item Number: H_ProductID
Description: H_ProductionDescrpt
Operation: H_Operation
Date of Issue: H_ProductionPackAppr
Sterility: H_Sterilitytype
Prod Pack Version: H_ProductionPackVers
Prod Pack Ver Date: H_ProductionPackDesc
Qty\Pkg: H_QuantityPerPackage

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

[redacted]

REF Reference Number 00-8400-095-00

Product Photo

Zimmer® Nexel™ Total Elbow

Articulation Kit Size 5,6

1 Axle Pin, 1 Humeral Bearing A, 2 Ulnar Bearings B

Use By 2019-09

Human Readable

REF Reference Number 00-8400-095-00 EDI: 00840009500 LOT Lot Number 99999999

Zimmer ® Nexel™ Total Elbow

Articulation Kit Size 5,6

1 Axle Pin, 1 Humeral Bearing A, 2 Ulnar Bearings B

Vivacit-E® Highly Crosslinked Polyethylene/Zimaloy® Co-Cr-Mo Alloy Sterile Qty-1

CE 0086 Single Use Attention, See Instructions for Use STERILE EO Sterilized Using Ethylene Oxide Rx only

Manufacturer

Zimmer® WARSAW, IN 46580, U.S.A.

Item Number: H_ProductID
Description: H_ProductionDescript
Operation: H_Operation
Date of Issue: H_ProductionPackAppr
Sterility: H_Sterilitytype
Prod. Pack Version: H_ProductionPackVers
Prod. Pack Ver Date: H_ProductionPackDesi
Qty\Pkg: H_QuantityPerPackage

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"Lot No"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #[redacted]-4653; Released by CDRH on 07/16/2017

Product Photo

REF Reference Number 00-8400-090-00
Zimmer® Nexel™ Total Elbow
Humeral Screw Kit
2 Humeral Screws
2019-09
V

LOT Lot Number 99999999 EDI: 00840009000 REF Reference Number 00-8400-090-00
Zimmer® Nexel™ Total Elbow
Humeral Screw Kit
2 Humeral Screws
Zimaloy® Co-Cr-Mo Alloy Sterile Qty-1
CE 0068 Single Use Caution, See Instruction Manual for Use STERILE R Sterilized Using Irradiation Rx only
Manufacturer
ZIMMER® WARSAW, IN 46580, U.S.A.

Item Number: V
Description: V
Operation: V
Date of Issue: V
Sterility: V
Prod. Pack Version: V
Prod. Pack Ver. Date: V
Qty\Pkg: V

V Products Table ver V V ver V

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Bar code 87-6204-077-99	Rx only	Rev. – September 2012 © 2012, Zimmer, Inc.

ZIMMER® NEXEL™ TOTAL ELBOW

zimmer	Zimmer, Inc. 1800 West Center Street Warsaw, Indiana 46580 USA 1-800-348-2759 (US only) +1-574-372-4999	EC REP Zimmer U K. Ltd. 9 Lancaster Place South Marston Park Swindon, SN3 4FP, UK	CE 0086

English

The CE mark is valid only if it is also printed on the product label

ZIMMER® NEXEL™ TOTAL ELBOW

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Before using a product placed on the market by Zimmer, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., product literature, written surgical technique). Zimmer is not liable for complications arising from the use of this device outside of its indicated uses, not aligned with the surgical technique, product selection or similar matters outside the control of Zimmer.

DESCRIPTION

This device is a total elbow prosthesis designed for use with bone cement. It is available in sizes 4, 5 and 6, in left and right configurations. The ulnar and humeral implant components are manufactured from *Tivanium®* Ti 6Al-4V alloy. The ulnar implant component has a porous coating of Ti-6Al-4V plasma spray and is curved to facilitate implantation. The humeral implant component has a porous coating of Ti-6Al-4V plasma spray and has an anterior flange to accommodate a bone graft. The linkage pin and screws are manufactured from *Zimaloy®* Co-Cr-Mo alloy. Vitamin E highly cross-linked ultra-high molecular weight polyethylene (*Vivacit-E®*) bearings prevent metal-to-metal articulating contact.

INDICATIONS

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- *Revision arthroplasty*

CAUTION: This device is intended for cemented use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

CONTRAINDICATIONS

Use of the *Zimmer Nexel* Total Elbow is contraindicated in patients with

- Currently active, or history of repeated, local infection at the surgical site
- Paralysis or dysfunctional neuropathy involving the elbow joint
- Significant ipsilateral hand dysfunction
- Excessive scarring of the skin or soft tissue that could prevent adequate soft tissue coverage
- Daily activities that would subject the device to significant stress (i.e., heavy labor, torsional stress, and/or competitive sports)

Relative contraindications include

- Distant foci of infection (e.g. genitourinary, pulmonary, skin [chronic lesions or ulcerations], or other sites). In cases of distant infection, the foci of infection should be treated prior to, during and after surgery
- Ancient prior sepsis

WARNINGS

- This device is for single patient use only. Do not reuse. Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.
- To properly implant this device, the surgical technique should be consulted and carefully followed
- Cementing technique is extremely important. The medullary canal should be copiously irrigated to remove blood, fat, and bone debris, and then thoroughly dried. A cement delivery system should be used to cement the humeral and ulnar implant components.
- A snug mechanical fit of the implant within the humeral and ulnar medullary canals may help minimize loosening of the implant components.
- The amount of bone removed from the ulna should be sufficient to permit full elbow motion on the operating table when the appropriate provisional prosthesis is fully inserted. The surgeon should check for full range of elbow motion at appropriate times during surgery.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PRECAUTIONS

- Proper handling of this implant is important. Contouring (bending) of the humeral or ulnar stems should be avoided. Any alteration may produce defects that could become focal points for excessive stresses leading to implant failure.
- To prevent late infection of total joint implants, many surgeons advise the use of antibiotic prophylaxis before and after dental manipulation, endoscopic examinations and other minor surgical procedures.
- Patients with significant lower extremity disability who require walking aids are less amenable to total elbow arthroplasty than patients with advanced and predominately upper extremity involvement.

ADVERSE EFFECTS

The following adverse effects have been reported:

- Early or late component loosening
- Implant failure or fracture
- Infection
- Nerve injury
- Triceps avulsion
- Cortical perforations and fractures
- Adverse tissue response and inflammatory reaction to the implant material or wear debris, including metal sensitivity
- Osteolysis and/or loosening due to wear debris

STERILITY

The *Zimmer Nexel* Total Elbow implants are provided sterile (the humeral and ulnar implant components, and the humeral screws are sterilized by gamma irradiation, indicated by the STERILE R symbol on the labeling, and, the articulation kit – including the bearings and the axle pin – is sterilized by ethylene oxide, indicated by the STERILE EO symbol on the labeling) and remain sterile until the expiration date displayed on the package, as long as the package integrity has not been violated. Inspect each package prior to use and do not use the implant component if any seal or cavity is damaged or breached or if the expiration date has been exceeded. Once opened, the implant component must be used, discarded or re-sterilized.

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STERILIZATION INSTRUCTIONS

These sterilization instructions are consistent with ANSI/AAMI/ISO standards and guidelines. They should be used for sterile items that were opened but unused

- Do not reuse implants
- In the event of inadvertent loss of sterility while preparing for surgery, all metal implant components may be re-sterilized only once for immediate use. This is subject to the exceptions listed below

  DO NOT RE-STERILIZE
  - Implant components that have been contaminated with body fluids or biologic debris, or that have been previously implanted
  - Implant components with a packaging expiration date that has been exceeded
  - Implant components containing *Vivacit-E* polyethylene
  - Any plastic, foam or polyethylene
- Do not use the original plastic cavities or lids for re-sterilization. Single implant components should be packaged in a medical grade sterilization pouch or wrap that conforms to the recommended specifications for steam sterilization provided in the table under *Recommended Sterilization/Re-sterilization Specifications* below. Ensure that the pouch or wrap is large enough to contain the implant component without stressing its seals or tearing
- Implant components must be disassembled and sterilized separately to minimize potential bio-burden buildup in the dead space and expansion/contraction stresses.
- Rinse implant components, paying special attention to porous coatings, to remove lint or other non-biologic debris using USP (United States Pharmacopeia) purified water

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Recommended Sterilization/Re-sterilization Specifications

Follow the sterilizer manufacturer's instructions for loading patterns and selection of sterilization parameters. Drying times vary according to load size and should be increased for larger loads.

For Single, All Metal Implants:

Steam Sterilization

Type	Temperature	Exposure Time	Minimum Dry Time
Gravity Displacement	121°C (250°F)	30 minutes	15 minutes
Gravity Displacement	132°C (270°F)	15 minutes	
UK Pre-vacuum/Pulsating Vacuum[1]	134°C (273°F)	3 minutes	
Pre-vacuum/Pulsating Vacuum	132°C (270°F)	4 minutes	

[1] This cycle is not for use in the United States

Please contact Zimmer at the following number if you have additional questions. In the USA, call 1-800-348-2759. For calls outside the USA, call the local international access code +1-574-267 6131

STERILIZATION PRECAUTIONS

- Aggressive cleaning with detergents and brushes may damage special features of the implants, such as porous coatings. Also, certain detergents may be difficult to rinse off polymer items, especially those made of silicone rubber.
- Items made from titanium and titanium alloys can form oxide layers from steam boiler treatment chemicals or detergent residues. While these oxides are biocompatible, they can obliterate identification etchings and stampings.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PATIENT COUNSELING INFORMATION

Complications and/or failure of prosthetic implants are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or with patients who fail to follow through with the required rehabilitation program. Physical activity can result in loosening, wear, and/or fracture of the implant. The prospective implant patient must be counseled about the capabilities of the implant and the impact it will have on his or her lifestyle. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities, and about the possibility that the implant or its components may wear out, fail or need to be replaced. The implant may not last the rest of the patient's life, or any particular length of time. Because prosthetic implants are not as strong, reliable, or durable as natural, healthy tissues/bones, all such devices may need to be replaced at some point.

Note: The prosthesis will not restore function to the level expected with a normal healthy joint and has functional limitations. Excessive muscular activity such as pounding and or carrying excessive loads must be avoided or restricted. The patient must not lift more than one pound (~0.5 kg) during the first three postoperative months, and, thereafter, not more than five pounds (~2.25 kg) with the operated arm. In addition, the risks and complications listed under ADVERSE EFFECTS must be explained to and discussed with the patient.

CAUTION: This device is intended for cemented use only.

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Preoperative Considerations

Indications/Contraindications

Short Version – Reference

Surgical Approach

Humeral Preparation

Ulnar Preparation

Trial Reduction

Bone Graft Preparation

Ulnar Component Implantation

Humeral Component Implantation

Closure

Postoperative Management

Revision Procedure

Scrub Nurse Instructions

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Pre-Operative Considerations

For those inexperienced in the technique of elbow arthroplasty, training with a cadaver specimen(s) is recommended

The surgeon should:

- Be aware of how to articulate and disarticulate the new coupling mechanism
- Understand the technique to place a bone graft beneath the anterior flange of the humeral component
- Be careful of implant sizing and cement technique in patients with pre-existing shoulder pathology
- Understand if a long humeral stem is to be implanted, stem modification may be needed if significant anterior bowing is noted on the lateral pre-operative radiographs
- Surgeon should consider counter-sinking the **Humeral Component** up to 10 mm proximal to the axis of rotation to help facilitate post-op range of motion
- The amount of bone removed from the ulna (including the tip of the olecranon and coronoid process) should be sufficient to permit full elbow motion on the operating table when the appropriate **Humeral** and **Ulnar Provisional** prostheses are fully inserted. The surgeon should check for full range of elbow motion at appropriate times during the surgery
- Be aware of pinch-points, sharp edges and secure handling of components (i.e. transferring components from back table to operating table) while assembling implants and utilizing instruments
- Be aware that size "5/6" instruments indicate that this instrument can be used for a Size 5 or 6 implant; likewise "4/5" indicates applicability to a Size 4 or 5 implant

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request #2016-4653; Released by CDRH on 07/16/2017

Indications / Contraindications

INDICATIONS

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

CAUTION: This device is intended for cemented use only

CONTRAINDICATIONS

Use of the Zimmer Nexel Total Elbow is contraindicated in patients with:

- Currently active, or history of repeated, local infection at the surgical site
- Paralysis or dysfunctional neuropathy involving the elbow joint
- Significant ipsilateral hand dysfunction
- Excessive scarring of the skin or soft tissue that could prevent adequate soft tissue coverage
- Daily activities that would subject the device to significant stress (i.e., heavy labor, torsional stress, and/or competitive sports)

Relative contraindications include:

- Distant foci of infection (e.g. genitourinary, pulmonary, skin [chronic lesions or ulcerations], or other sites). In cases of distant infection, the foci of infection should be treated prior to, during and after surgery.
- Ancient prior sepsis

WARNINGS

- This device is for single patient use only. Do not reuse. Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.
- To properly implant this device, the surgical technique should be consulted and carefully followed.
- Cementing technique is extremely important. The medullary canal should be copiously irrigated to remove blood, fat, and bone debris, and then thoroughly dried. A cement delivery system should be used to cement the humeral and ulnar implant components.
- A snug mechanical fit of the implant within the humeral and ulnar medullary canals may help minimize loosening of the implant components.
- The amount of bone removed from the ulna should be sufficient to permit full elbow motion on the operating table when the appropriate provisional prosthesis is fully inserted. The surgeon should check for full range of elbow motion at appropriate times during surgery.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Short Version - Reference

Include a page of mostly images (cliff notes version of technique right up front)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Chapter 1: Surgical Approach

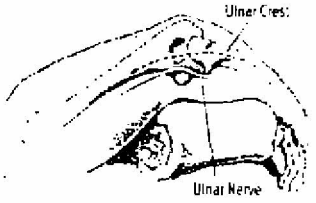
1.0 Tourniquet

- Apply the tourniquet

1.1 Incision

- Position
  - The recommended position is supine, with a sandbag or rolled towel under the scapula and arm placed across the chest
- Initial incision
  - Make a *straight* incision over the elbow joint, approximately 15cm in length
  - Center the incision just lateral to the tip of the olecranon (Figure 1.1)

Note: a more mid-line positioned incision decreases the need for elevating extensive flap



Make incision with cut lateral to midline.

Figure 1.1

1.2 Protect the Ulnar Nerve

- Identify the ulnar nerve
  - Identify the medial aspect of the triceps mechanism and isolate the ulnar nerve using ocular magnification
- Transpose the ulnar nerve
  - Mobilize the ulnar nerve well proximally and distally to the first motor branch and carefully translocate it anteriorly into the subcutaneous tissue (Figure 1.2)
  - Utilize the bipolar cautery for hemostasis
  - Incise or excise a small portion of the medial intramuscular septum

Note: The nerve must be carefully protected throughout the remainder of the procedure

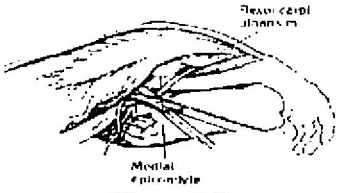


Figure 1.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The Bryan-Morrey Approach

The standard surgical approach employs Bryan/Morrey exposure and is recommended for new users of the New Zimmer Total Elbow system and users inexperienced with power rasping. The Bryan/Morrey approach employs a meticulous repair of the triceps that is detailed at the end of this surgical technique. Once experience is gained, other exposures (e.g. Triceps-On/Sparing and Triceps-Split) and/or power-rasping of the medullary canals can be employed at the surgeon's discretion.

- Release the triceps
  - Make an incision just medial to the crest of the ulna and elevate the ulnar periosteum along with the triceps and forearm fascia (Figure 1.3A)
  - Dissection proceeds laterally insuring that the triceps remains in continuity with the periosteum and fascia
  - Sharpey's fibers are carefully released and the anconeus elevated from its ulnar insertion

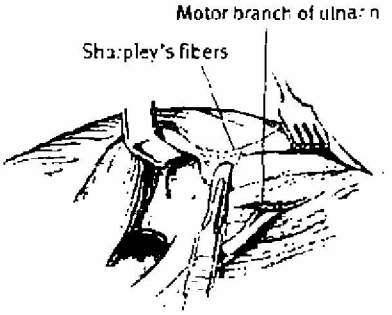

Figure 1.3A

- Visualize the joint
  - Dislocate the entire extensor mechanism (triceps, ulnar periosteum, and anconeus) as a single soft-tissue sleeve laterally
  - This allows complete exposure of the posterior aspect of the distal humerus, proximal ulna, and radial head (Figure 1.3B)
  - Release the anterior capsule and contracted soft tissue from the distal humerus to eliminate any flexion contracture. (Figure 1.3C)

Figure 1.3B

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Figure 1.3C

- Disarticulate the ulnohumeral joint
  - Subcutaneously release the medial and lateral collateral ligaments from their humeral attachment
  - Flexion of the elbow to disarticulate the ulna from the humerus (Figure 1.3D)
  - If further visualization is required, external rotation of the forearm can facilitate exposure of contracted soft-tissue

Note: A complete release of the soft tissues around the medial side of the distal humerus is intended to protect the medial epicondyle (the weakest part of the distal humerus) from fracture during flexion and manipulation of the forearm. Elbows with severe arthritis, post-traumatic surgery, and/or asymptomatic soft-tissue contractures should have the entire capsule and soft tissues from the distal humerus circumferentially released subcutaneously.

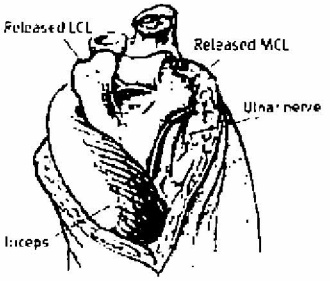

Figure 1.3D

Chapter 2: Humeral Preparation

2.0 Resect the Trochlea

- Visualize the width and location of the initial resection
  - Hold the barrel of the central portion of the **Humeral Awl Reamer** against the trochlea and visually align the long axis of the instrument with the long axis of the humerus (Figure 2.0A)
- (Scrub Nurse will load appropriately sized saw blade)
- Resect approximately 20 mm of the middle portion of the trochlea using a saw or rongeur (Figure 2.0B)
  - The width of the resection should be sufficient to avoid impingement of the **Humeral Rasp**
  - Retain trochlear bone for anterior distal bone graft (Chapter 5)

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Tip: The bone graft, which measures 3-5mm thick, can be cut by first making a center cut, followed by additional oblique medial & lateral cuts. One of these slices can be used as the anterior flange bone graft

Figure 2.0A

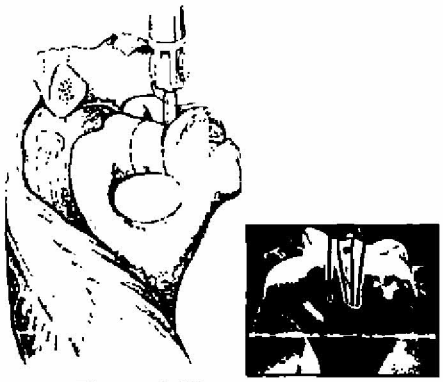

Figure 2.0B

2.1 Expose the Humeral Medullary Canal

- Use a bur or rongeur to penetrate a small portion of cortical bone from the proximal roof of the olecranon fossa (Figure 2.1)
- Proceed with control until cancellous bone can be seen

Figure 2.1

2.2 Ream the Humeral Medullary Canal

- Insert the shaft of the **Humeral Awl Reamer** into the humeral medullary canal and lightly twist in order to open the canal and verify the axis (Figure 2.2)
    - The barrel of the **Humeral Awl Reamer** should be centered and fit through the previous trochlear cut, otherwise remove more bone until it fits

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Figure 2.2

*Note: the barrel on the central portion of the **Humeral Awl Reamer** ensures clearance for the width of the largest **Humeral Rasp***

2.3 Humeral Canal Preparation

- *(Scrub Nurse section will describe how to attach Rasps)*

*Note: The posterior face of the **Rasp** should be kept parallel to the plane formed by the posterior cortices of the medial and lateral columns. If these landmarks are not available, the relatively flat posterior surface of the shaft of the distal humerus can also be used to approximate this plane (Figure 2.3A)*

*Note: The orientation of the **T-Handle** can be altered 90 degrees to suit surgeon preference*

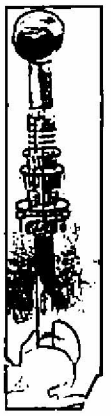

Figure 2.3A&B

- Advance the **Pilot Humeral Rasp** manually until it meets resistance, then gently impact it proximally into the canal until the solid etched line on the **Rasp** aligns with the anatomic axis of flexion (Figure 2.3B) (*see pre-op considerations*)
- Serial rasping continues until the **Rasp** fits snugly in the canal at a depth at which the flexion axis is in alignment with the solid etched line on the **Rasp**

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- Confirm **Humeral Rasp** alignment by inserting the larger diameter end of the **I/E Alignment Rod** through the **Humeral Rasp** to verify it is in same plane as the posterior cortices or the flat posterior surface of the distal humerus if cortices not present (Figure 2.3C)
- **Do not remove the final Humeral Rasp from the canal as it is used to direct the trephine cut below**

*Note: The **Rasps** are marked to indicate implant features (Figure 2.3C)*

*Tip: **Flexible Cannulated Reamers** are available to safely enlarge the canal if even the smallest **Rasp** is too large for the canal*

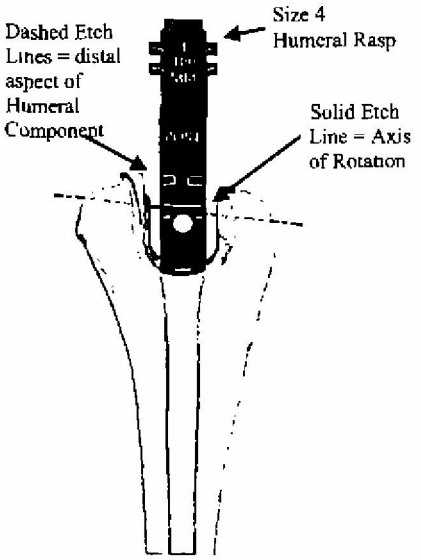

Figure 2.3C

2.4 Preliminary Trephine Cut

- Choose the appropriately sized **Trephine,** either a Size 4 or 5/6 based on the final **Rasp** utilized
- Insert its pilot pin of the **Trephine** into the hole of the **Humeral Rasp** (Figure 2.4A)

Tip: the use of a high speed attachment is recommended

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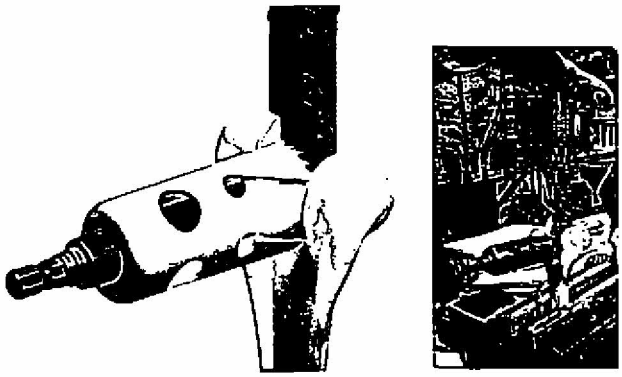

Figure 2.4A

Note: Size 4 ***Trephine*** *has a slightly different diameter than the Size 5/6 Trephine to prevent mismatch from occurring between the* ***Trephine*** *and* ***Humeral Rasp***

- Start **Trephine** drill before its teeth are engaged in the posterior humeral bone, then gently advance until the pilot pin reaches its depth stop (Figure 2.4B)
    - This will score the posterior surface and serve as a guide for the final **Trephine** cut. Leave bone fragments in place

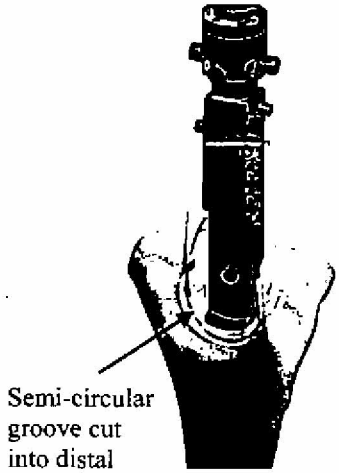

Figure 2.4B

2.5 Make Vertical Cuts

- Attach the appropriate **Humeral Cut Guide** to the **Humeral Rasp;** choose Size 4 or 5/6 (Note: if depth of rasp insertion adjustments are desired, be sure to impact the T-Handle and not the Cut Guide)
- Stabilize the **Humeral Cut Guide** with the **Humeral Bearing Driver Pin** (Figure 2.5A&B)

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Figure 2.5A

- Using the slots of the **Humeral Cut Guide,** make required medial and lateral cuts; this determines the final width of the humeral preparation (Figure 2.5B)
- Remove the instruments

Note: for the final version of the surgical technique, this image will show the Humeral Cut Guide and Rasp and Saw Blade, with humerus. It will also show retractors to protect soft tissues and to avoid saw blade.

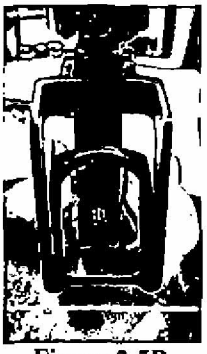

Figure 2.5B

2.6 Finish the Trephine Cut

- Insert the appropriately sized **Trephine Stabilizer** into the humeral medullary canal and align the center of the **Trephine Stabilizer** hole with the center of previous trephine cut; choose from Size 4 or 5/6 (Figure 2.6A)
- Drill until **Trephine** pilot pin reaches the depth stop
- Remove instruments and bone fragments (Figure 2.6B)

Figure 2.6A

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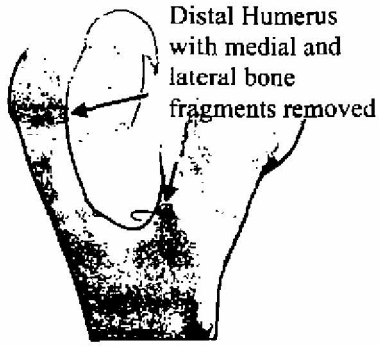
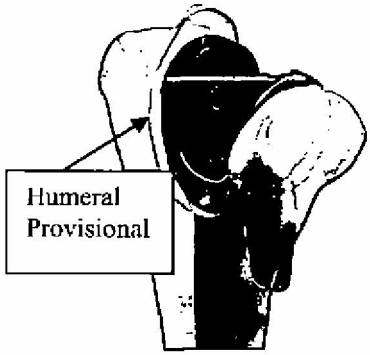


Figure 2.6B

2.7 Assess depth and orientation of the Humeral Provisional

- Do not cement
- Place the appropriate **Humeral Provisional** into the prepared humeral canal (Figure 2.7A)
    - Ensure that the **Humeral Provisional** is fully seated (impaction should not be required), the flexion axis is in the proper position, and that it does not sit proud relative to the distal aspect of the lateral humeral condyle
- Trim any excess condylar bone distal to the provisional with rongeurs
- Remove instruments



Note: for the final version of the surgical technique, this image will demonstrate a "proud" provisional, and will show where to "trim".

Figure 2.7A

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Chapter 3: Ulnar Preparation

3.0 Ulnar Canal Preparation

- Remove the tip of the olecranon (Figure 3.0A) and use a high-speed bur to penetrate cortical bone at the base of the coronoid to enter the intramedullary canal (Figure 3.0B)
- Create a "notch" along the guiding ridge of the ulna. This is a critical step to avoid placement of the ulnar component in a flexed position
- Place a finger over the exposed proximal shaft of the ulna to help prevent violation of the medullary canal in anticipation of the ulnar bow (Figure 3.0C)
- Carefully advance the **Ulnar Awl Reamer** axially into the medullary canal (Figure 3.0D)

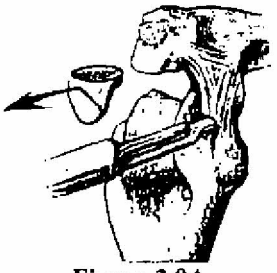

Figure 3.0A

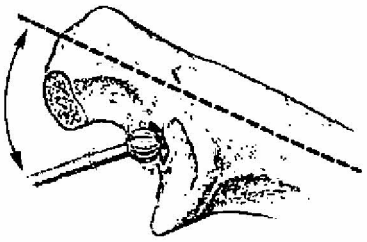

Figure 3.0B

Figure 3.0C

Note: for the final version of the surgical technique, this image will be updated to show in situ

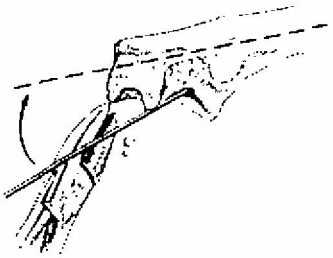

Figure 3.0D

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3.1 Ulnar Canal Reaming (if necessary)

*Note: the 4.5mm **Reamer** is prescribed for the size 4 implant; the 6.5 **Reamer** for the size 5, and; the 7.0 **Reamer** for the size 6 ulnar devices.*

Reamers must be used in progressively larger cutting head sizes. Always begin with the 4.5mm solid reamer. DO NOT skip sizes, or attempt to begin with larger cutting head sizes.

- Advance the 4.5 mm **Flexible Solid Reamer** carefully until the etch line of the desired **Ulnar Component** length (75, 90, or 115mm) reaches the entrance to the ulnar canal (distal to the greater sigmoid notch) (Figure 3.1A)

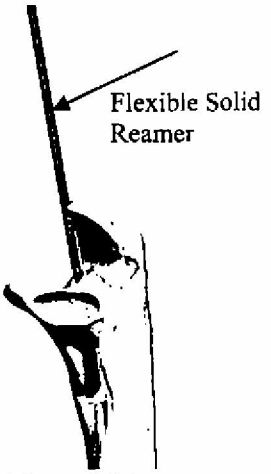

Figure 3.1A

- Continue to ream canal sequentially
  - **Flexible Solid Reamers** are size 4.5mm and 5mm, while **Flexible Cannulated Reamers** are sizes 5.5 – 7.0mm (Figure 3.1B)

Note: Flexible Cannulated Reamers require use with a **Sterile Ball Tip Guide Wire 2.4 x 70** to ensure proper tracking and control depth of insertion

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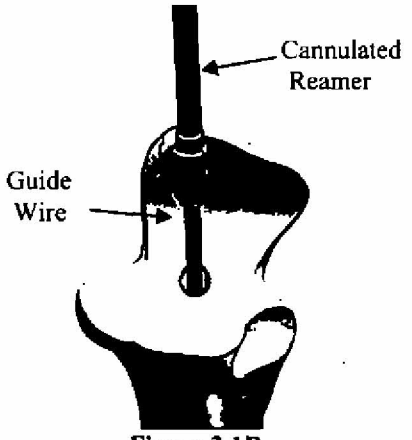
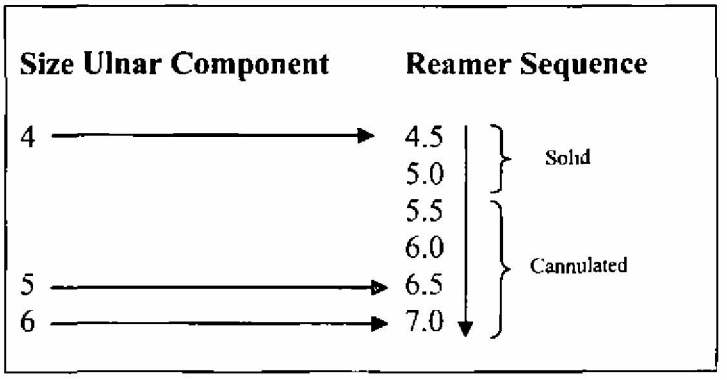


Figure 3.1B



3.2 Rasp the proximal ulnar canal

- Attach **T-Handle** to the **Pilot Ulnar Rasp** and properly orient the **Rasp** in both the coronal and sagittal planes; choose from left or right **Ulnar Rasp** configurations (Figure 3.2A)
- Confirm **Ulnar Rasp** alignment by inserting the narrow end of the **I/E Alignment Rod** through the **Ulnar Rasp** to verify it is parallel to the relatively flat surface of the posterior aspect of the Olecranon (Figure 3.2A)
- Advance the **Pilot Ulnar Rasp** manually until it meets resistance, then gently impact it distally into the canal until the center of the Ulnar eye is aligned to the projected center of the greater sigmoid notch
- Continue with sequential rasping until the proper size has been determined (Size 4/5 **Rasp** is the final **Rasp** used for a Size 4 or 5 implant; Size 6 **Rasp** is the final **Rasp** used for a Size 6 implant)
- Leave the final **Rasp** in canal

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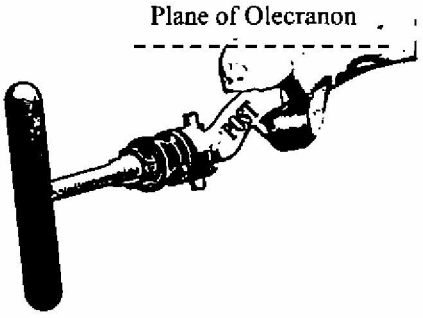

Figure 3.2A

*Note: Features and markings on the medial, lateral and posterior faces of the **Rasps** correspond to characteristics of the **Ulnar Component** (Figure 3.2B)*

Image show Ulnar Component along side ulnar rasp demonstrating the feature similarities

Figure 3.2B

3.3 Sigmoid Notch Preparation

- Place **Ulnar Clearance Template** through the Ulnar eye feature of the **Rasp** from the medial and lateral side in order to ensure adequate clearance for **Ulnar Bearings** and final assembly step (Figure 3.3)
- Remove any impinging bone to allow for proper seating of the **Humeral Component**

Figure 3.3

3.4 Assess the accuracy of the ulnar canal preparation

- Do not cement
- Place **Ulnar Provisional** into the ulnar canal (impaction should not be required) and confirm that the center of the circular head of the **Ulnar Provisional** is concentric with the projected center of the greater sigmoid notch (Figure 3.4A)
    - **Humeral Bearing Driver Pin** can be used to assess proper internal/external alignment (Figure 3.4B)
- Do not remove the **Ulnar Provisional** once proper seating is established

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Image will show ulnar provisional in ulna, lateral view and the distal (transverse view) showing into of humeral bearing driver pin sliding into through hole

Figure 3.4A&B

Chapter 4: Trial Reduction

- Do not cement
- Re-insert the appropriate **Humeral Provisional** into the humerus
- Slide the **Ulnar Provisional** into the **Humeral Provisional** (Figure 4.0)
- Perform a trial range of motion
- Remove any bone impingements (possibly including portions of the radial head) with a bur or rongeur and perform any soft tissue release as needed

*Note: **Provisionals** will not lock together and will not mate with implants. Causes for incomplete restoration of elbow extension include too distal orientation of humeral joint axis, inadequate depth of insertion of ulnar provisional, unresolved angular deformity, inadequate release of anterior soft-tissue contracture and posterior bone impingement*

Figure 4.0

Chapter 5: Bone Graft Preparation

- A bone graft is fashioned from an excised trochlea or radial head
- Trim graft to size with an oscillating saw or rongeur
    - Approximately 2-3mm thick, 2 cm long and 1-1.5mm wide (Figure 5.0)

Bone graft

Figure 5.0

Chapter 6: Ulnar Component Implantation

- Clean the ulnar canal with copious irrigation to remove blood, fat and bone debris, and then thoroughly dry.
- Cut the cement tube to the length of the **Ulnar Component** (Figure 6.0A)

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- Use a retrograde technique to fill canal with cement
    - Leave approximately 1 cm of the proximal canal free of cement to avoid excessive backflow

Tip: to help avoid porosity in the cement mantle, use finger to compress the cement into the canal (gauze will protect glove from cement.) Trim the cement tube flush with the nozzle, apply the nozzle to the canal and continue injecting cement until cement visibly backflows around nozzle, clear the excess cement

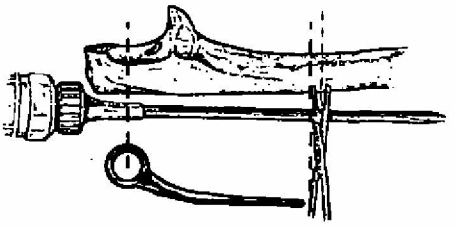

Figure 6.0A

- Insert the **Ulnar Component** so the center of Ulnar eye is aligned with the projected center of the greater sigmoid notch (Figure 6.0B)
    - Carefully impact **Ulnar Component** with the **Ulnar Stem Inserter** to fully seat
    - Use the Quick Use Curette to thoroughly remove any extruded bone cement displaced by the stem insertion
- DO NOT install the **Articulation Assembly** (consisting of the Ulna Component, Axle-Pin and two Ulnar Bearings) until after the **Ulnar Component** has been placed properly in the canal and all bone cement has been removed from the exposed articulation area

This sagittal image will show the ulnar component in the ulna and will show the quick-use Currette.

Figure 6.0B

Chapter 7: Humeral Component Implantation

*Note: The **Humeral Component** is cemented. The plasma spray yoke and anterior flange is for bone growth. No cement is utilized on these surfaces.*

- (Scrub Nurse will install the Humeral Bearing into the Humeral Component)
- Prep the canal by using copious irrigation to remove blood, fat and bone debris, and then thoroughly dry
- Place cement restrictor in place
- Inject bone cement using a retrograde fill technique
    - Cut the cement tube to the length of the **Humeral Component** (Figure 7.1A)

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- Apply cement to a depth 2 cm distal to the tip of the length of the **Humeral Component** ; leave approximately 1 cm of the distal canal free of cement to avoid excessive backflow

Alternative Method: to help avoid porosity in the cement mantle, use finger to compress the cement into the canal (gauze will protect glove from cement.) Trim the cement tube flush with the nozzle, apply the nozzle to the canal and continue injecting cement until cement visibly backflows around nozzle, clear the excess cement

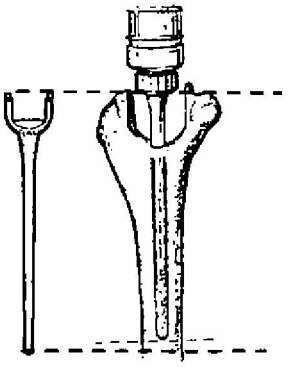

Figure 7.1A

- Insert the **Humeral Component** into the medullary canal
  - Wedge the bone graft between the flange of the **Humeral Component** and the anterior distal humeral cortex
  - Ensure the graft is engaged by the Humeral flange during insertion
- Carefully impact the **Humeral Component** securely in place with the **Humeral Stem Inserter** (Figure 7.1B)
- Clear any excess bone cement
  - **Pay special attention to remove cement from the posterior hole on the humerus that is used to remove the humeral bearing during revision cases**

Note: for the final version of the surgical technique, this image will show the humeral component with preloaded Humeral Bearing. It will also label the Humeral stem inserter.

Figure 7.1B

7.2 Attach the Bearings/Axle-Pin to Ulnar Component

- (Scrub Nurse will prepare Bearing Assembly at back-table)
- Perform installation in situ, after the **Ulnar Component** has been cemented in place

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- Introduce the prepared **Ulnar Bearings/Axle-Pin** Assembly to the implanted **Ulnar Component**
  - **Use caution to avoid contact between the Axle-Pin and the Ulnar eye to avoid scratching the eye's surface** (Figure 7.2A)

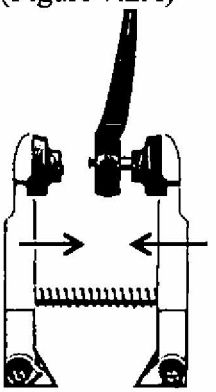

Figure 7.2A

- Squeeze the handles of the **Ulnar Bearing Assembly Tool** until the **Axle-Pin** has been fully seated into the opposing **Ulnar Bearing** and resistance is felt

Note: A visual cue on the handle will confirm when the stopping point for Size 4 and 5/6 has been met (Figure 7.2B)

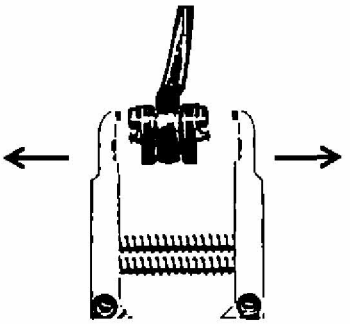

Figure 7.2B

Note - the following changes will be made to this image for the final version of the surgical technique: Ghost an ulna to show in-situ. Label Size 5/6 stopping point.

7.3 Reduce the Elbow

- Allow cement to cure
- Apply the feet of the **Articulation Inserter** to the pocketed tabs of the **Ulnar Bearings** and partially reduce the joint by guiding the ends of the **Axle-Pin** into the Humeral yoke (Figure 7.3A)
- Line up the **Ulnar Bearing** tabs with the **Humeral Component** slots
- While maintaining the **Articulation Inserter's** feet on the **Ulnar Bearings,** insert the peg of the proximal leg of the **Articulation Inserter** into the hole at the base of the Humeral yoke (Figure 7.3B)
- Squeeze the handle of the **Articulation Inserter** to drive the **Ulnar Bearings** into the Humeral yoke, ensuring that the tabs of the **Ulnar Bearings** maintain alignment with the slots of the Humeral yoke throughout insertion (Figure 7.3C)
- Remove tools

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*Note: The **Ulnar Bearing Tamp** is an alternate tool available to assist with this step*

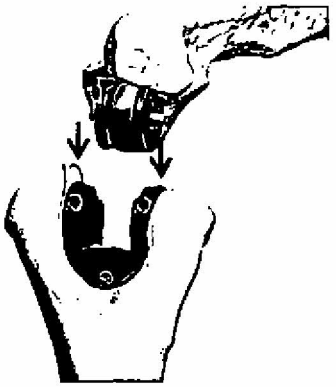

Figure 7.3A&B

This image shows peg into revision hole on humeral. Label eye

Figure 7.3C

This image shows squeezing components together. Label eye

Figure 7.3D

- **Avoid contact of the Ulnar eye with the Articulation Inserter**
- Full insertion is achieved when the surfaces of the Ulnar Bearings appear to be flush with the distal Humeral yoke (Figure 7.3E)

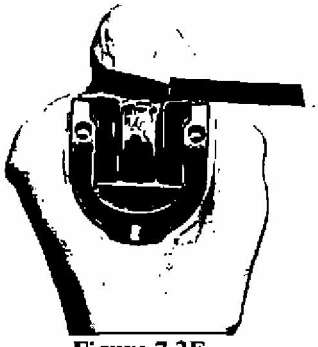

Figure 7.3E

Note - the following edits will be made for the final version of the surgical technique: show inset of the screw hole ghosted and the position of the Axle pin to demonstrate how the screws ride above axle.

7.4 Insert Humeral Screws

Do not tighten screws with an alternate driver, do not use power. Use the tools provided in the instrument set to insert screws. Proper application of torque to install the Humeral Screws is required for a successful implant.

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- (Scrub Nurse will prepare the Screws/Screw Holder and Driver Bit/Driver)
- Insert each screws from the **Humeral Screw Holder** and into the **Humeral Component** yoke (Figure 7.4A)
    - Turn the **Driver** until the first screw is free of the instrument (7.4B)
    - Repeat process with the second screw
    - Tighten the screws in two sequences (screw 1 then screw 2, followed by screw 1 and screw 2 again) with the **Driver** until an abrupt loss of torque is felt
    - The **Driver Bit** is designed to yield when the appropriate torque is applied to the screw, utilizing a protective sleeve to keep both parts of the yielded bit contained
    - The **Driver Bits** are designed and calibrated for single-use/single-surgery

*Note: An optional **Elbow Torque Driver** may be used, which will produce an audible "click" once torque has been achieved; Elbow Torque Driver is designed for single-use/single-surgery*

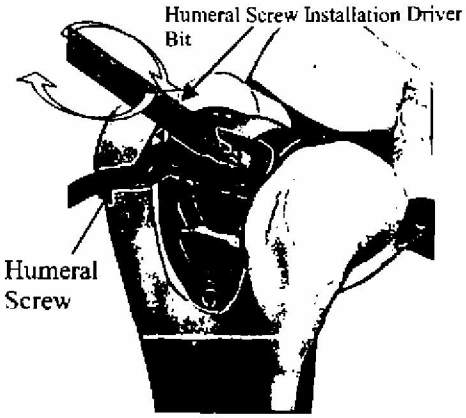

Figure 7.4A

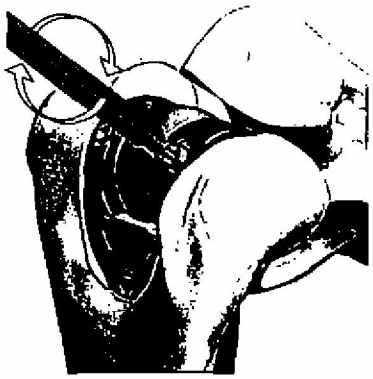

Figure 7.4B

7.5 Perform final range of motion

- Perform a final range of motion
- Remove any bone impingements (possibly including portions of the radial head) with a bur or rongeur and perform any soft tissue release as needed

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Chapter 8: Closure

8.0 Close the Wound

- Repair the Triceps (Figures 8.0A-E)
  - Slightly over correct the triceps mechanism to its anatomic position
  - Place cruciate and transverse holes in the proximal ulna
  - Use a heavy #5 nonresorbable suture in a crisscross fashion
  - A transverse suture compresses the triceps against the olecranon
  - Tie sutures with the elbow in approximately 45 degrees of flexion
- Complete the closure in a routine fashion
  - Stabilize the ulnar nerve in the subcutaneous anterior pocket
  - Deflate the tourniquet and obtain hemostasis
  - Close the wound in layers
  - Insert a drain, if desired
- Finish closure
  - Apply a compressive dressing and split with the elbow in full extension

Figure 8.0A

Figure 8.0B

Figure 8.0C

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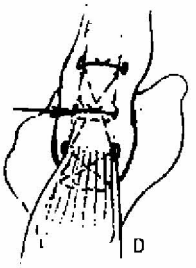

Figure 8.0D

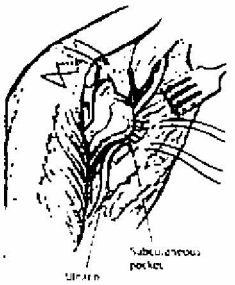

Figure 8.0E

Chapter 9: Postoperative Management

9.1 Postoperative Management

- Apply a light dressing and elevate arm
- 24 hours
  - Remove the drain, if used, at approximately 24 hours
- 36-48 hours
  - Remove the compressive dressing on the second day after surgery
  - Instruct the patient on activities of daily living
    - Typically, no formal physical therapy is required or indicated unless necessary for the shoulder or hand
    - Avoid strengthening exercises
    - Allow elbow flexion and extension as tolerated
- 1-3 Days
  - Elevate the arm postoperatively for one to three days as necessary
- 4-8 weeks
  - If a greater than 45 degree flexion contracture was present before surgery, use an extension brace at night for 4-8 weeks
- First 3 months
  - The patient must not lift more than one pound (~0.5 kg) during the first three postoperative months
  - Lifting in flexion is not an issue
- After 3 months
  - It is recommended the patient not lift more than 1 kg (2 lbs) on a repetitive basis or more than 2.5 kg (5 lbs) as a single event

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Chapter 10: Revision Technique

10.0 Disarticulate the joint

- (Scrub Nurse will prepare the Driver Bit/Removal Driver)
- Remove the two **Humeral Screws** using the **Humeral Screw Removal Driver and Bit** (Figure 10.0A)
- Insert the **Articulation Extractor** between the **Humeral Bearing** and one of the **Ulnar Bearings** and gently pry (do not impact) to separate the Articulation (Figure 10.0B)
- Remove the **Axle-Pin** by using a rongeur to grasp one end of the **Axle-Pin** and pull it out of the **Articulation Assembly** with other hand (Figure 10.0C)

*Note: An optional **Elbow Torque Driver** may be used to remove the **Humeral Screws***

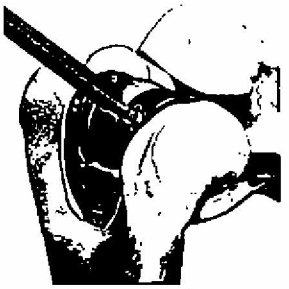

Figure 10.0A

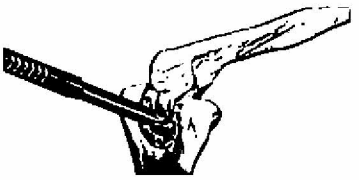

Figure 10.0B

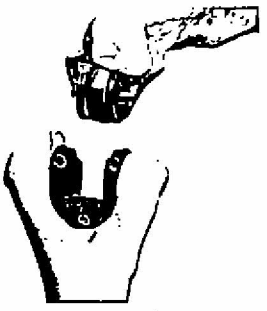

Figure 10.0C

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10.1 Ulnar Component Removal

- Insert the **Implant Extractor Hook** into the eye of the **Ulnar Component** and remove the ulnar component with the **Slide Hammer** (Figure 10.1 A&B)

Figure 10.1A

Figure 10.1B

10.2 Humeral Component Removal

- Remove the **Humeral Bearing** by inserting the tip of the **Humeral Bearing Extractor** into the hole just below the **Humeral Bearing**
- Gently push (do not impact) the handle down to dislodge the bearing from the base of the **Humeral Component** yoke (Figure 10.2A)

Image will show the humeral bearing extractor, peg in humeral bearing revision hole. Label "push "

Figure 10.2A

- Attach **Humeral Extractor Plate** (choose Size 4 or 5/6) by inserting two **Humeral Extractor Screws** into the holes on the posterior side of the **Humeral Component** (Figure 10.2B) and lightly tighten with the **Small Hex Screwdriver**

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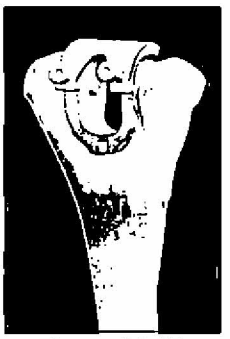

Figure 10.2B

Note – for the final version of the surgical technique, this image will show the Humeral Extractor Plate being assembled to the Humeral Component, with screws and driver in image.

- Insert the **Implant Extractor Hook** under the **Humeral Stem Extractor Plate** and remove with the **Slide Hammer** (Figure 10.2C)

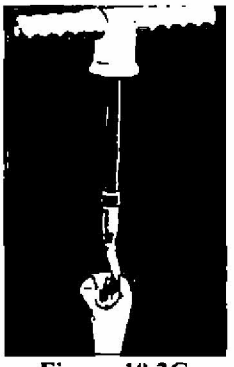

Figure 10.2C

10.3 Poly Swap

- Place the **Humeral Bearing** using the **Humeral Bearing Placement Tool** (Figure 10.3A)
- Fully seat the **Humeral Bearing** by carefully impacting with the **Humeral Bearing Driver** (Figure 10.3B) or alternatively using the **Articulation Inserter** (Figure 10.3C)
    - Confirm no visual gaps between the **Humeral Bearing** and the Humeral yoke
- Finish procedure using primary technique

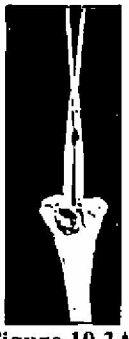

Figure 10.3A

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Figure 10.3B

This image will show the Articulation Inserter pressing the bearing in place

Figure 10.3C

Chapter 11: Scrub Nurse Instructions

Note: Perform all tasks at the back-table

11.0 Saw Blades

- Attach a .050" thick oscillating saw blade (1.27 mm thick) to power equipment for use during the Humeral Preparation

11.1 Rasp Connections

- Attach the Rasp to the **T-Handle** (Figure 11.1A)

Figure 11.1A

- *Alternatively, if power-rasping is employed, connect one end of the **Reciprocating Saw Adapter** to the drill and the other end to the **Single-Use Connector**, which then connects to **Rasp** (Figure 11.1D&E)*

Show single-use connector attachment to quick connect

Figure 11.1D

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Attachment to the recip saw

Figure 11.1E

11.2 Humeral Bearing Assembly

- Once Humeral Component size has been determined, place the **Humeral Bearing** into the **Humeral Component** using the **Humeral Bearing Placement Tool** (Figure 11.2A)
  - The **Humeral Bearing** does not have a specific anterior or posterior orientation
  - The **Humeral Bearing** will not appear to be fully seated at this stage

Figure 11.2A

Note – for the final version of the surgical technique, this image will show the Humeral Bearing being placed into the Humeral Component by the Humeral Placement Tool. Shows handles, no bone in this image (just humeral component).

- Position the **Humeral Bearing Driver** against articulation surface of the **Humeral Bearing** and insert the **Humeral Driver Pin** (Figure 11.2B)
  - Keep Driver handle parallel to the Humeral Component rotation axis
  - Allow the loose ring to drop into the pockets of the Humeral yoke to help stabilize the device
- Turn the handle approximately ¼- revolution or about 90-degrees until the **Humeral Bearing** is fully seated
  - Resistance will be felt, but *no* audible click will occur
  - **Humeral Bearing** will be fully seated when there are no visual gaps when viewing from the posterior and the anterior sides of the Humeral yoke (Figure 11.2C)
- Remove the Instruments

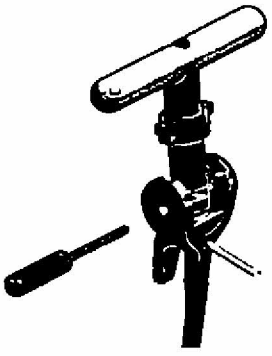

Figure 11.2B

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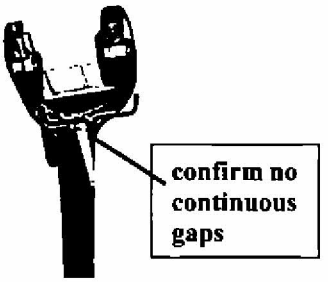

Figure 11.2C

- Alternatively, position the **Articulation Inserter** against the articulation surface of the **Humeral Bearing** and insert the peg of the proximal leg of the **Articulation Inserter** into the hole at the base of the Humeral yoke (Figure 11.2D)

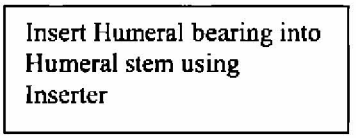

Figure 11.2D

- Squeeze the handles to fully seat the **Humeral Bearing** (Figure 11.2E)

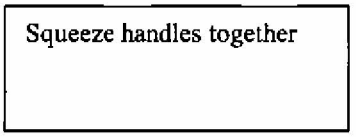

Figure 11.2E

11.3 Ulnar Bearing/Axle-Pin Assembly

- Load an **Ulnar Bearing** (same box as **Humeral Bearing**) into one side of the **Ulnar Bearing Assembly Tool**, and one end of the **Axle-Pin** into the hole in the opposite jaw of the tool (Figure 11.3)
- Grasp **Axle-Pin** with your fingers and squeeze the handles together with the other hand until hard resistance is felt

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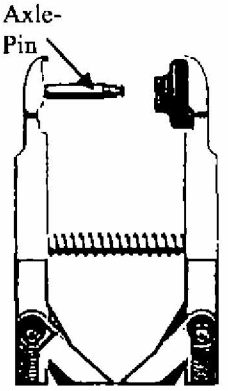

Figure 11.3

- Load second **Ulnar Bearing (DO NOT** squeeze the second bearing onto the Axle-Pin)
- Carefully introduce the **Ulnar Bearing Assembly Tool**, with **Ulnar Bearing/Axle** and second **Ulnar Bearing** pre-loaded to the surgeon

11.4 Load Screws

- Insert the **Humeral Screws** into the **Humeral Screw Holder** by gently threading them in place using the applied flexible tubing to provide tactility (Figure 11.4)
- Remove and discard tubing from screws

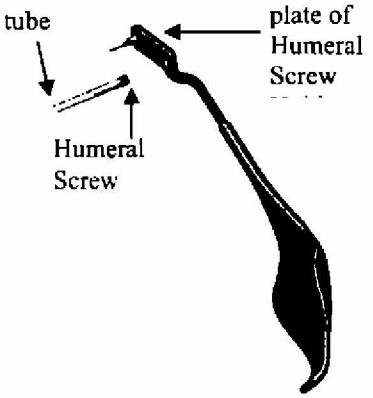

Figure 11.4

11.5 Prepare the Humeral Screw Installation Driver

- Load the **Humeral Screw Installation Driver Bit** into the **Humeral Screw Installation Driver** (Figure 11.5)
- Do not remove the plastic sleeve from the **Installation Driver Bits**

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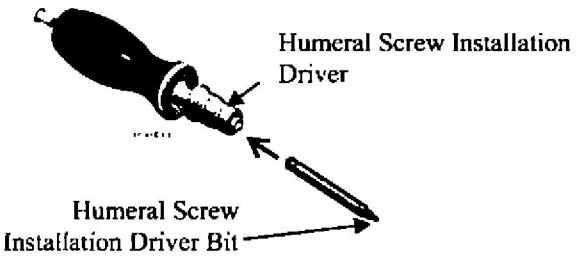

Figure 11.5

11.6 Prepare the Humeral Screw Removal Driver

- Load the **Humeral Screw Removal Driver Bit** into the **Humeral Screw Removal Driver** (Figure 11.6)

Image shows the connection of the humeral screw removal bit into the humeral screw removal driver

Figure 11.6

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sterilization

The Zimmer Nexel Total Elbow is sterilized in the following four groupings: the humeral component, ulnar component, the humeral screws (2 in a package) and the articulation kit (humeral bearing-A, 2 ulnar bearings-B and an axle pin). The humeral component, ulnar component and humeral screws are sterilized using Gamma Irradiation (^{60}Co) at a contract sterilizer. The articulation kit is sterilized using Ethylene Oxide Gas processing at a contract sterilizer.

Sterilization Method for Humeral Component, Ulnar Component and Humeral screws

The Zimmer Nexel Total Elbow humeral component, ulnar component and humeral screws will be terminally sterilized by gamma irradiation (^{60}Co). The minimum to maximum dose range is 25.0-37.0 kGy. The minimum sterilization dose will be verified using VDmax^{20} and the gamma irradiation processing and dose mapping were conducted using the following standards:

- ANSI/AAMI/ISO 11137-1:2006, "Sterilization of health care products – Radiation – Requirements for development, validation and routine control of a sterilization process for medical devices."
- ANSI/AAMI/ISO 11137-2:2006, "Sterilization of health products – Radiation – Establishing the sterilization dose."
- AAMI TIR 33:2005, "Sterilization of health care products – Radiation – Substantiation of a selected sterilization dose – Method VDmax."

The products will be accepted for release as sterile through the methods stated above to provide a sterility assurance level (SAL) of 10^{-6} or better.

Sterilization Method for the Articulation Kit

The Zimmer Nexel Total Elbow articulation kit, which consists of three polyethylene components (1 humeral bearing-A and 2 ulnar bearings-B) and an axle-pin, will be terminally sterilized by ethylene oxide (EtO) sterilization and sold sterile.

EtO – Sterilization cycles are validated per appropriate requirements of ANSI/AAMI/ISO 11135-1:2007, *Sterilization of health care products – Ethylene Oxide Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.* Ethylene Oxide residuals analysis will be conducted to meet the requirements of ANSI/AAMI/ISO 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.*

As part of the sterilization validations for EtO sterilization, a residuals analysis dissipation curve test will be conducted on the subject device.

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The products will be accepted for release as sterile through the methods stated above to provide a sterility assurance level (SAL) of 10^{-6} or better.

Re-sterilization of the polyethylene components (humeral bearing-A and ulnar bearings-B) is not recommended under any circumstance.

The following standards are applicable:

- ANSI/AAMI/ISO 11135:2007, Sterilization of Health care products – Ethylene Oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ANSI/AAMI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals
- AAMI TIR 28:2009 – Product adoption and process equivalency for Ethylene Oxide sterilization

Shelf Life

The shelf life of the packaging for the Zimmer Nexel Total Elbow humeral component, ulnar component and humeral screws (note: the "humeral screws" are also referred to as the "humeral screw kit") is 10 years. The shelf life of the articulation kit (the humeral bearing-A, humeral bearings-B and the axle pin) is 5 years. This testing was performed according to ASTM F1980 *Standard Guide for Accelerated Aging for Sterile Medical Device Packages* and ANSI/AAMI/ISO 11607:2006 *Packaging for Terminally Sterilized Medical Devices*. The packaging materials demonstrate no degradation over time and the shelf life test data assures sterile packaging integrity.

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Biocompatibility

The materials contained in the proposed device along with the standards to which they conform are listed and clinically referenced below:

Material Used	Zimmer Specification (ZES)	Conformance Standard
Zimaloy (Co-Cr-Mo)	2A-74	ASTM F1537
Tivanium (Ti-6Al-4V)	2A-81	ASTM F136
Plasma Spray (Ti-6Al-4V)	2A-51	ASTM F1580
IonGuard® (nitrogen ion surface enrichment)	2A-65	NA
Vivacit-E™ *Vit-E HXPE* (Vitamin-E blended highly crosslinked polyethylene)	2B-124	NA

These materials, used in the implants, have been shown to be acceptably compatible with biological tissues through previous clinical usage in orthopedic implant applications:

- *Zimaloy* is identical to that used in existing, previously cleared components, such as Coonrad-Morrey Total Elbow – Ulnar and Humeral Implants manufactured by Zimmer, Inc (K001989, cleared July25,2000)
- *Tivanium* is identical to that used in existing, previously cleared components such as Coonrad-Morrey Total Elbow – Ulnar and Humeral Implants manufactured by Zimmer, Inc (K001989, cleared July25,2000)
- Plasma spray is identical to that used in existing, previously cleared components such as Coonrad-Morrey Total Elbow – Ulnar Implants manufactured by Zimmer, Inc (K001989, cleared July25,2000)
- *IonGuard*® for Titanium material is identical to that used in existing, previously cleared components such as Natural Knee System - manufactured by Zimmer (K853991, cleared Feb21,1986).
- *Vivacit-E*™ Vit-E HXPE is identical to that used in existing, previously cleared components such as *Vivacit – E*,Vitamin E Highly Crosslinked Polyethylene Liners manufactured by Zimmer, Inc (K120370, cleared June4, 2012)

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Software

This device is an orthopaedic implant and contains no associated software.

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Electromagnetic Compatibility and Electrical Safety

This device does not contain any electronic components; therefore, this section does not apply.

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V.2

Performance Testing - Bench

Testing specific to Vivacit-E™ (Vitamin E [α-tocopherol] stabilized, high crosslinked ultra-high molecular weight polyethylene) is contained within the Vitamin E Stabilized HXPE Material Master File authored by Zimmer (FDA Ref: MAF-1868).

Testing specific to plasma spray for the humeral component is contained within the Plasma Sprayed Titanium-6Al-4V Alloy Coating Material Master File (FDA Ref: MAF-1909, Letter of Authorization can be found in Section 21).

Testing specific to plasma spray for the ulnar component is contained within the Coatings Characterization of Orthopedic Titanium 6Al4V Coatings Material Master File (FDA Ref: MAF-652, Letter of Authorization can be found in Section 22).

Consistent with clinically observed failure modes, the Zimmer Nexel Total Elbow test strategy was based on the following keys to clinical success: stem loosening[1], stem fatigue, bearing wear, system durability and modular connection fatigue and resistance to disassociation. Testing methodology was informed by internationally recognized standards, FDA guidance documents, previous testing, biomechanical rationales, peer-reviewed journal articles and predicate device retrieval studies.

Testing was conducted on the proposed device (the Zimmer Nexel Total Elbow) and compared to a legally marketed predicate device (the Zimmer Coonrad/Morrey Total Elbow). The proposed device functioned as intended and met all acceptance criteria, thus demonstrating that the Zimmer Nexel Total Elbow is as safe and effective as the legally marketed Zimmer Coonrad/Morrey Total Elbow.

In addition to conducting the aforementioned device-specific bench testing to substantiate substantial equivalence of the proposed device to the predicate, testing was conducted to evaluate the delamination resistance of Vivacit-E (Vit-E HXPE) as compared to that of conventional GUR 1050 Ultra High Molecular Weight Polyethylene. The conclusions of this testing and the associated proposed marketing claim are presented below, after the device-specific testing summaries.

Testing is summarized below, and the full test reports are included at the end of this section.

[1] Note: Although, it is a recognized mode of failure for total elbow arthroplasty, stem loosening was not the focus of a performance test for the New Zimmer Total Elbow, because the variables (stem geometry, material and surface finish) associated with stem loosening are consistent from the predicate to the proposed device; and, therefore the proposed device (the New Zimmer Total Elbow) is expected to be as safe and effective as the predicate device (the Coonrad/Morrey Total Elbow) in terms of ability to resist stem loosening.

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Note: The "Zimmer Nexel Total Elbow" may also be referred to as the "Lunar Elbow" (an internal project name used in lieu of a brand name), "The New Zimmer Total Elbow", "New Zimmer Elbow", "New Elbow", "Zimmer Total Elbow", "Zimmer New Elbow" and the "proposed device". The "Zimmer Coonrad/Morrey Total Elbow" may also be referred to as the "Coonrad/Morrey", the "C/M" and the "predicate device".

Stem Fatigue Testing

Humeral Stem Fatigue Testing

Testing Documentation

- Zimmer Research Report ZRR_WA_2554_12, *Coonrad/Morrey Elbow Distal Humeral and Proximal Ulnar Implant Stem Fatigue Testing*
- Zimmer Research Report ZRR_WA_2589_12, *New Zimmer Total Elbow Humeral Implant Distal Stem Fatigue Testing*

Cumulative Conclusions of Testing Documentation

- The Zimmer Nexel Total Elbow is as safe and effective as the predicate device (Zimmer Coonrad/Morrey Total Elbow) in terms of humeral stem fatigue strength.
- The fatigue strength of the Zimmer Nexel Total Elbow humeral component stem at (b)(4) load cycles is (b)(, which is (b)(stronger than that of the legally marketed Zimmer Coonrad/Morrey Total Elbow humeral component (b)(4) at a comparable point on the stem.

Background

Due to a lack of fatigue testing standards specific to the humeroulnar joint and because both the proposed device (the Zimmer Nexel Total Elbow) and the predicate device (the Zimmer Coonrad/Morrey Total Elbow) are indicated for use with the same weight-in-hand (5 lbs), the purpose of this set of tests was to ensure that, under worst-case loading conditions, the fatigue strength of the proposed device (Zimmer Nexel Total Elbow) is as safe and effective as that of the predicate device (the Zimmer Coonrad/Morrey Total Elbow).

The humeral component was fatigue tested in the distal region of the stem (the beaded region on the predicate device, and the plasma spray region on the Zimmer Nexel Elbow), because this is consistent with the location of humeral stem fractures observed and reported clinically.

Methods

First, a test was conducted to determine the fatigue strength at (b)(4) load cycles in the beaded region of the predicate device's humeral component.

The Zimmer Nexel Total Elbow humeral component was then fatigue tested in the same manner as the predicate device; and, the fatigue strength of the proposed device was compared to that of the predicate device.

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Results

The predicate device humeral component was fatigue tested at various load levels, and the fatigue strength was determined to be (b)(4) confidence. The full test report can be found in at the end of this section under Zimmer Research Report ZRR_WA_2554_12, *Coonrad/Morrey Elbow Distal Humeral and Proximal Ulnar Implant Stem Fatigue Testing*.

Five Zimmer Nexel Total Elbow humeral stems achieved (b)(4) load cycles at (b)(4) without fracture. The full test report can be found at the end of this section under Zimmer Research Report ZRR_WA_2589_12, *New Zimmer Total Elbow Humeral Implant Distal Stem Fatigue Testing*.

Device Update

The following update was made to the humeral component of the Zimmer Nexel Total Elbow device after the conclusion of humeral stem fatigue testing and may be considered theoretically relevant to the outcome of the test, but this update was determined to have no impact on testing results or cumulative conclusions of testing documentation.

Humeral Stem Fatigue Testing, Update 1 (Humeral Component):

The plasma spray pattern has changed slightly, specifically the termination of plasma spray coating has been moved posteriorly to more closely reflect the beaded pattern of the predicate device. See Images 18.1 and 18.2 below.

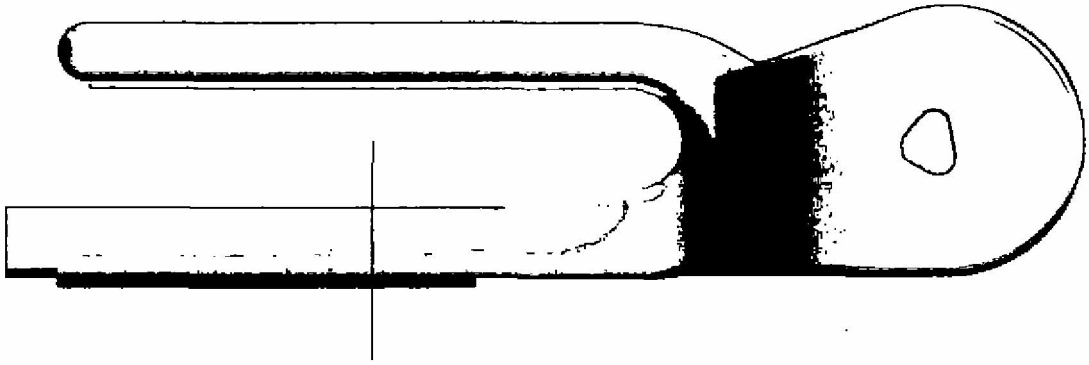

Image 18.1 Humeral Stem Fatigue Testing, Update 1 (blue line is potting level, gray represents plasma spray region on the **humeral components tested in this study**)

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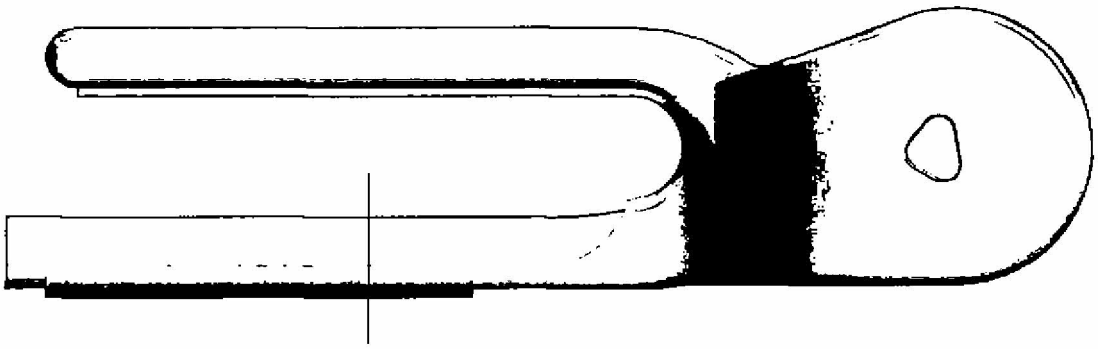

Image 18.2 Humeral Stem Fatgue Testing, Update 2 (blue line is potting level, gray represents plasma spray region on **current Zimmer Nexel Total Elbow** production-intent humeral component)

Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: Because the plasma spray coating reduces the fatigue strength of Tivanium [Zimmer Technical Memo 1222.00, *Fatigue Strength of Plasma Sprayed Ti-6AL-4V Alloy Material*], moving the plasma spray away from the anterior side (the region that experiences maximum tensile stress) would tend to further reduce the likelihood of a fatigue fracture in the high stress zone; therefore, this update is numerically negligible with respect to the results and conclusions associated with this test.

Internal References

The following research documents, internal to Zimmer, informed this fatigue testing and are provided for reference in their entirety at the end of this section under:

- Zimmer Research Memo ZRM_WA_0292_11, *Summary of Clinical Complications of the Coonrad/Morrey Elbow System*
- Zimmer Research Report ZRR_WA_2476_11, *Biomechanics Rationale for the Loading of Total Elbow Prosthesis During In Vitro Simulations*
- Zimmer Technical Memo 1218.00, *Coonrad/Morrey Humeral Stem Fatigue Testing*
- Zimmer Technical Memo 1222.00, *Fatigue Strength of Plasma Sprayed Ti-6AL-4V Alloy Material*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ulnar Stem, Mid-Stem Fatigue Testing

Testing Documentation

- Zimmer Research Report ZRR_WA_2585_12, *Coonrad/Morrey Elbow Ulnar Implant Mid-Stem Fatigue Testing*
- Zimmer Research Report ZRR_WA_2615_12, *New Zimmer Total Elbow Ulnar Implant Mid-Stem Stem Fatigue Testing*

Cumulative Conclusions of Testing Documentation

- The Zimmer Nexel Total Elbow is as safe and effective as the predicate device (Zimmer Coonrad/Morrey Total Elbow) in terms of ulnar stem mid-stem fatigue strength.
- The fatigue strength of the Zimmer Nexel Total Elbow ulnar component stem in the mid-stem region at (b)(4) load cycles is at least the same as that of the legally marketed Zimmer Coonrad/Morrey Total Elbow ulnar component at a comparable point on the stem (b)(4).

Background

Due to a lack of fatigue testing standards specific to the humeroulnar joint and because both the proposed device (the Zimmer Nexel Total Elbow) and the predicate device (the Zimmer Coonrad/Morrey Total Elbow) are indicated for use with the same weight in hand (5 lbs), the purpose of this set of tests was to ensure that, under worst-case loading conditions, the fatigue strength of the proposed device (Zimmer Nexel Total Elbow) is as safe and effective as that of the predicate device (the Zimmer Coonrad/Morrey Total Elbow).

The ulnar component was subjected to testing along the mid-stem (also referred to as "tapered", "distal", and "non plasma spray") region of the stem to ensure that the Zimmer Nexel Total Elbow ulnar component (which, unlike the predicate device, was subjected to a nitrogen enrichment hardening process) remained as safe and effective as the predicate device in terms of fatigue strength in this mid-stem region.

Methods

First, a test was conducted to determine the fatigue strength in the mid-stem (non plasma spray region) of the predicate device's ulnar component.

The Zimmer Nexel Total Elbow ulnar component was then fatigue tested in the same manner as the predicate device; and, the fatigue strength of the proposed device was compared to that of the predicate device.

Questions? Contact CDRH FOI Staff/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Results

The predicate device ulnar component was fatigue tested at various load levels, and the fatigue strength in the mid-stem region was determined to be (b)(, as 1 predicate device fractured at (b)(4) achieved (b)(4) load cycles at (b)(without fracture. The full test report can be found at the end of this section under Zimmer Research Report ZRR_WA_2585_12, *Coonrad/Morrey Elbow Ulnar Implant Mid-Stem Fatigue Testing*.

(b) Zimmer Nexel Total Elbow ulnar stems achieved (b)(4) load cycles in the mid-stem region at a load of (b)(4 without fracture. The full test report can be found at the end of this section under Zimmer Research Report ZRR_WA_2615_12, *New Zimmer Total Elbow Ulnar Implant Mid-Stem Stem Fatigue Testing*.

Device Updates

The following update was made to the components of the Zimmer Nexel Total Elbow device after the conclusion of ulnar stem mid-stem fatigue testing and may be considered theoretically relevant to the outcome of the test, but these updates were determined to have no impact on testing results or cumulative conclusions of testing documentation.

Ulnar Stem Mid-Stem Fatigue Testing, Update 1 (Ulnar Component):
On the size 4 and size 5 ulnar implants, approximately (b)(4) of material was removed from the anterior side and approximately (b)(4) of material was added to the posterior side of the neck region (the proximal-most aspect of the ulnar stem, closest to the ulnar eye). Similarly, on the size 6 ulnar implant, approximately (b)(4 of material was removed from the anterior side and approximately (b)(4) of material was added to the posterior side of the neck region. This design change was made to increase the overall flexion-extension range of motion to (b)(for all ulnar-humeral implant combinations. See Image 18.3 below.

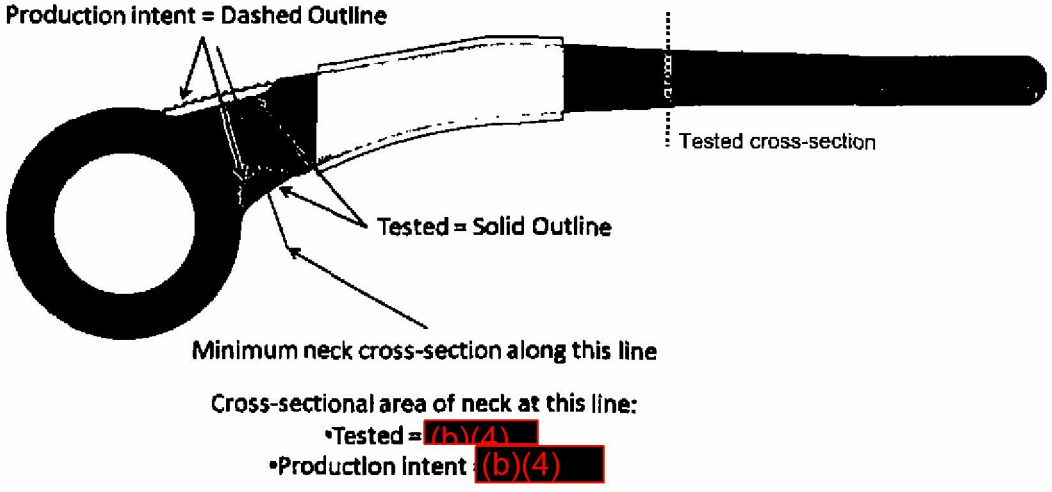

Image 18.3: Ulnar Stem Mid-Stem Fatigue Testing, Update 1

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Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This change reduced the cross-sectional area of the size 4 ulnar component (worst case tested in the ulnar stem mid-stem fatigue test) in the neck region from (b)(4) Because this change does not affect the *dimensions* at the tested cross-section, it neither alters the moment of inertia nor the moment arm created by the worst-case test orientation; therefore, the stresses at the test location are also not expected to change. Therefore, this update is numerically negligible with respect to the results and conclusions associated with this test.

Internal References

The following research documents, internal to Zimmer, informed this fatigue testing and are provided for reference in their entirety at the end of this section under:

- Zimmer Research Memo ZRM_WA_0292_11, *Summary of Clinical Complications of the Coonrad/Morrey Elbow System*
- Zimmer Research Report ZRR_WA_2476_11, *Biomechanics Rationale for the Loading of Total Elbow Prosthesis During In Vitro Simulations*
- Zimmer Technical Memo 1217.00, *Coonrad/Morrey Elbow Ulnar Stem Fatigue Testing*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ulnar Stem, Proximal Fatigue Testing

Testing Documentation

- Zimmer Research Report ZRR_WA_2554_12, *Coonrad/Morrey Elbow Distal Humeral and Proximal Ulnar Implant Stem Fatigue Testing*
- Zimmer Research Report ZRR_WA_2626_12, *New Zimmer Total Elbow Ulnar Implant Proximal Stem Fatigue Testing*

Cumulative Conclusions of Testing Documentation

- The Zimmer Nexel Total Elbow is as safe and effective as the predicate device (Zimmer Coonrad/Morrey Total Elbow) in terms of ulnar component stem fatigue strength in the plasma spray (proximal stem) region.
- The fatigue strength of the Zimmer Nexel Total Elbow ulnar component stem in the plasma spray (proximal stem) region at (b)(4) load cycles is at least the same as that of the legally marketed Zimmer Coonrad/Morrey Total Elbow ulnar component at a comparable point on the stem (b)(4), and thus meets the performance requirement for substantial equivalence for the ulnar component stem in the plasma spray region.
- The fatigue strength of the Zimmer Nexel Total Elbow ulnar component stem in the plasma spray (proximal stem) region at (b)(4) load cycles is (b)(4) (a load equivalent to (b)(4) weight-in-hand), which exceeds the performance requirement for substantial equivalence for the ulnar component stem in the plasma spray region.

Background

Due to a lack of fatigue testing standards specific to the humeroulnar joint and because both the proposed device (the Zimmer Nexel Total Elbow) and the predicate device (the Zimmer Coonrad/Morrey Total Elbow) are indicated for use with the same weight in hand (5 lbs), the purpose of this set of tests was to ensure that, under worst-case loading conditions, the fatigue strength of the proposed device (Zimmer Nexel Total Elbow) is as safe and effective as that of the predicate device (the Zimmer Coonrad/Morrey Total Elbow).

The ulnar component was fatigue tested in the plasma spray region of the stem, because this is consistent with the location of ulnar stem fractures observed and reported clinically.

Methods

First, a test was conducted to determine the fatigue strength of the predicate device ulnar component in the plasma spray (proximal stem) region.

The Zimmer Nexel Total Elbow ulnar component was then fatigue tested in the same manner as the predicate device; and, the fatigue strength of the proposed device was compared to that of the predicate device.

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Results

The predicate device ulnar component was fatigue tested at various load levels, and the fatigue strength in the plasma spray (proximal stem) region was determined to be (b)(4), as 1 predicate device fractured at (b)(4) 1 fractured at (b)(4) 1 fractured at (b)(4) and (b)(4) load cycles at (b)(4) without fracture. The full test report can be found at the end of this section under Zimmer Research Report ZRR_WA_2554_12, *Coonrad/Morrey Elbow Distal Humeral and Proximal Ulnar Implant Stem Fatigue Testing*.

(b)(4) Zimmer Nexel Total Elbow ulnar stems achieved (b)(4) load cycles in the plasma spray (proximal stem) region at a load of (b)(4) without fracture, meeting the performance requirement. In addition, five Zimmer Nexel Total Elbow ulnar stems achieved (b)(4) load cycles in the plasma spray (proximal stem) region at a load of (b)(4) (a load equivalent to (b)(4) lbs weight-in-hand) without fracture. The full test report can be found at the end of this section under Zimmer Research Report ZRR_WA_2626_12. *New Zimmer Total Elbow Ulnar Implant Proximal Stem Fatigue Testing*.

Device Updates

The following update was made to the components of the Zimmer Nexel Total Elbow device after the conclusion of ulnar stem proximal fatigue testing and may be considered theoretically relevant to the outcome of the test, but these updates were determined to have no impact on testing results or cumulative conclusions of testing documentation.

Ulnar Stem Proximal Fatigue Testing, Update 1 (Ulnar Component):
On the size 4 and size 5 ulnar implants, approximately (b)(4)" of material was removed from the anterior side and approximately (b)(4)" of material was added to the posterior side of the neck region (the proximal-most aspect of the ulnar stem, closest to the ulnar eye). Similarly, on the size 6 ulnar implant, approximately (b)(4) of material was removed from the anterior side and approximately (b)(4) of material was added to the posterior side of the neck region. This design change was made to increase the overall flexion-extension range of motion to (b)(4) for all ulnar-humeral implant combinations. See Image 18.4 below.

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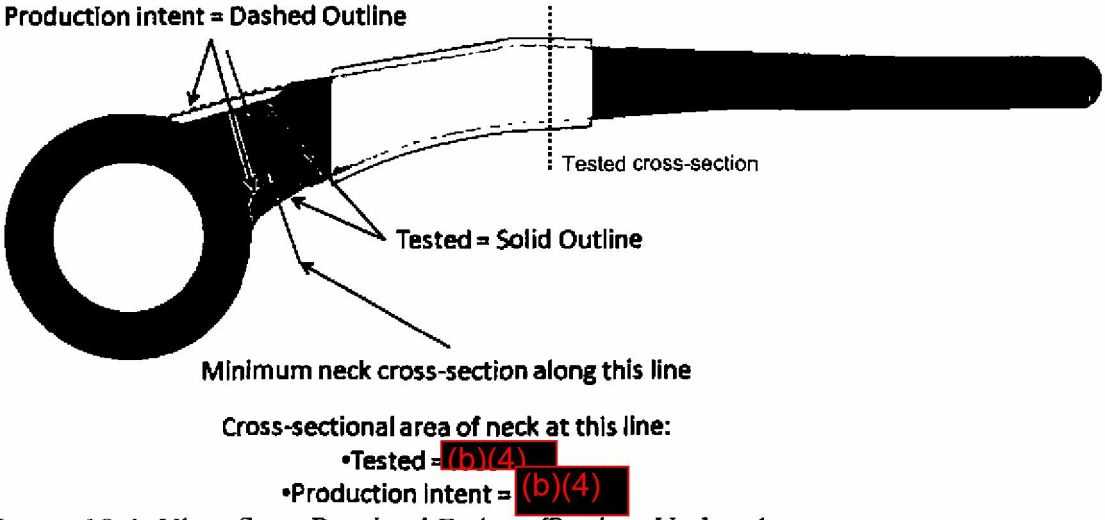

Image 18.4: Ulnar Stem Proximal Fatigue Testing, Update 1

Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This change reduced the cross-sectional area of the size 4 ulnar component (worst case tested in the ulnar stem proximal fatigue test) in the neck region from (b)(4). Because this change does not affect the dimensions at the tested cross-section (in the plasma spray region), it neither alters the moment of inertia nor the moment arm created by the worst-case test orientation; therefore, the stresses at the test location (in the plasma spray region) is also not expected to change.

This rationale for why this device update does not create a new worst case in the ulnar stem proximal fatigue testing is further substantiated by an additional finite element analysis performed (ZRR_WA_2648_12), which concluded that the peak tensile stresses (during similar clinically-relevant worst-case loading conditions) in the neck region of the production-intent Nexel ulnar component remain below the experimentally demonstrated material fatigue strength of wrought Tivanium. Therefore, this update is numerically negligible with respect to the results and conclusions associated with this test.

Internal References

The following research documents, internal to Zimmer, informed this fatigue testing and are provided for reference in their entirety at the end of this section under:

- Zimmer Research Memo ZRM_WA_0292_11, *Summary of Clinical Complications of the Coonrad/Morrey Elbow System*
- Zimmer Research Report ZRR_WA_2476_11, *Biomechanics Rationale for the Loading of Total Elbow Prosthesis During In Vitro Simulations*
- Zimmer Technical Memo 1217.00, *Coonrad/Morrey Elbow Ulnar Stem Fatigue Testing*
- Zimmer Research Report ZRR_WA_2648_12, *Finite Element Analysis of Nexel Elbow Ulnar Implant Neck Region*

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Wear Testing

Testing Documentation

- Zimmer Research Report ZRR_WA_2407_11, *Coonrad/Morrey Wear Test Method*
- Zimmer Research Report ZRR_WA_2552_12, *Wear Testing of the New Zimmer Total Elbow Prosthesis*

Cumulative Conclusions of Testing Documentation

- The Zimmer Nexel Total Elbow met or exceeded all acceptance criteria and is at least as safe and effective as the predicate device in terms of wear performance.
- The Zimmer Nexel Total Elbow mean gravimetric wear rate (b)(4) at (b)(4) load cycles) was (b) less than that of the predicate.

Background

Due to a lack of wear testing standards specific to the humeroulnar joint, a wear test was developed by Zimmer that produces results on the Zimmer Coonrad/Morrey Total Elbow polyethylene bearings similar to those observed on clinically retrieved Zimmer Coonrad/Morrey Total Elbow polyethylene bearings (the full test report can be found at the end of this section under Zimmer Research Report ZRR_WA_2407_11, *Coonrad/Morrey Wear Test Method*).

The same wear test was then conducted using the proposed (Zimmer Nexel Total Elbow) device in order to ensure that the proposed device is equal to or better than the predicate device (the Zimmer Coonrad/Morrey Total Elbow) in terms of gravimetric wear results. The full test report can be found at the end of this section under Zimmer Research Report ZRR_WA_2552_12, *Wear Testing of the New Zimmer Total Elbow Prosthesis*.

Methods

(b)(4) proposed device (Zimmer Nexel Total Elbow) articular assemblies were tested at (b)(with a loading profile shown to produce clinically relevant results for the predicate device (the Zimmer Coonrad/Morrey Total Elbow). This testing on the proposed device was conducted in four intervals and the gravimetric wear rate determined at (b)(4) cycles. In addition, the test lubricant was salvaged from (b)(4) randomly selected stations at the (b)(4) cycle milestones and the polyethylene debris isolated and compared to the debris obtained from the same test conducted on the predicate device.

The Zimmer Nexel Total Elbow was required to complete this test regime without component fracture, device disassembly, or evidence of metal-on-metal articulation. Additionally, the Zimmer Nexel Total Elbow was required to complete this test with a

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mean gravimetric wear rate equal to or less than that of the predicate device ((b)((b)(4) . Finally, all humeral screws were required to have measureable torque upon removal at the conclusion of testing.

Results

All (b)(4) Zimmer Nexel Total Elbow test specimens completed the testing protocol without incidences of component fracture, disassembly or evidence of metal-on-metal articulation and with isolated poly debris similar in shape (aspect ratio, AR) and size (equivalent circle diameter, ECD) as compared to the poly debris isolated from the predicate device wear test. The Zimmer Nexel Total Elbow mean gravimetric wear rate (b)(4) load cycles) was (b)(less than that of the predicate devic (b)(4) load cycles). All humeral screws had measureable torque upon removal at the conclusion of testing.

Device Updates

The following updates were made to the components of the Zimmer Nexel Total Elbow device after the conclusion of wear testing and may be considered theoretically relevant to the outcome of the test, but these updates were determined to have no impact on testing results or cumulative conclusions of testing documentation.

Wear Testing, Update 1 (Ulnar Component):

The width of the flat surface on the inner diameter of the ulnar eye increased slightly from (b)(4) (causing an overall inner diameter increase of the ulnar eye by (b)(4)) in order to improve load distribution and ensure the allowable minimum pistoning (proximodistal and anteroposterior translational) motion of the proposed device is no less than that of the predicate device. See Image 18.5 below.

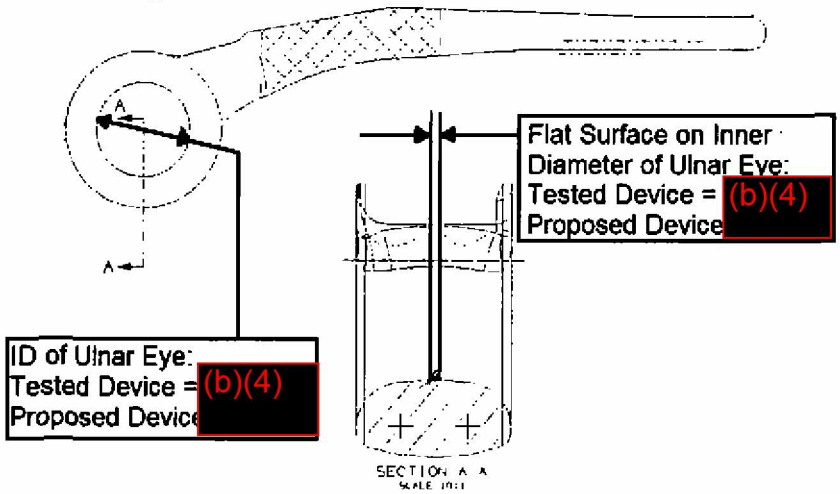

Image 18.5: Wear Testing, Update 1

Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: The surfaces affected by this update did not articulate against the ulnar bearings-B components during this wear test as a result of

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the fixed varus/valgus position of the ulnar component with respect to the poly and humeral components dictated by the clinically-relevant worst-case test method; therefore, this update is numerically negligible with respect to the results and conclusions associated with this test.

Wear Testing, Update 2 (Ulnar Component):
The mediolateral radial dimension of the ulnar eye was increased by (b)(4) (causing a decrease of the anteroposterior outer diameter of the ulnar eye by (b)(4) to improve load distribution. See Image 18.6 below.

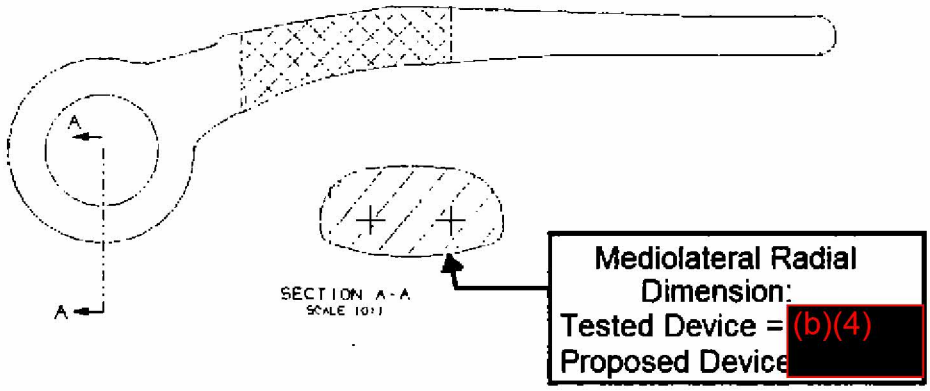

Image 18.6: Wear Testing, Update 2

Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This update is numerically negligible with respect to the results and conclusions associated with this test.

Wear Testing, Update 3 (Ulnar Bearings-B):
The compressible semi-circle design feature was originally only on one of the ulnar bearings (ulnar bearing-B). This compressible semi-circle was then added to the second ulnar bearing (originally called ulnar bearing-C) in order to make the two ulnar bearings identical and avoid the potential use error of choosing the wrong of two nearly identical components. See Image 18.7 below.

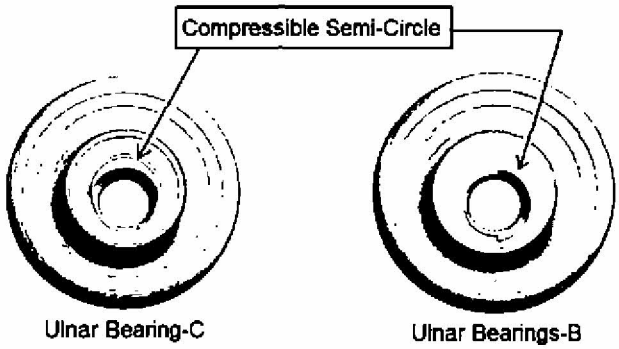

Image 18.7: Wear Testing, Update 3

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Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This update only very slightly improved the overall press-fit between apposing ulnar bearings-B and between ulnar bearings-B and the humeral yoke, making this update numerically negligible with respect to the results and conclusions associated with this test.

Wear Testing, Update 4 (Ulnar Bearings-B):
The distance between the major external face and the minor internal face was decreased by (b)(4) to ensure non-interference between the broad faces of apposing ulnar bearings-B. See Image 18.8 below.

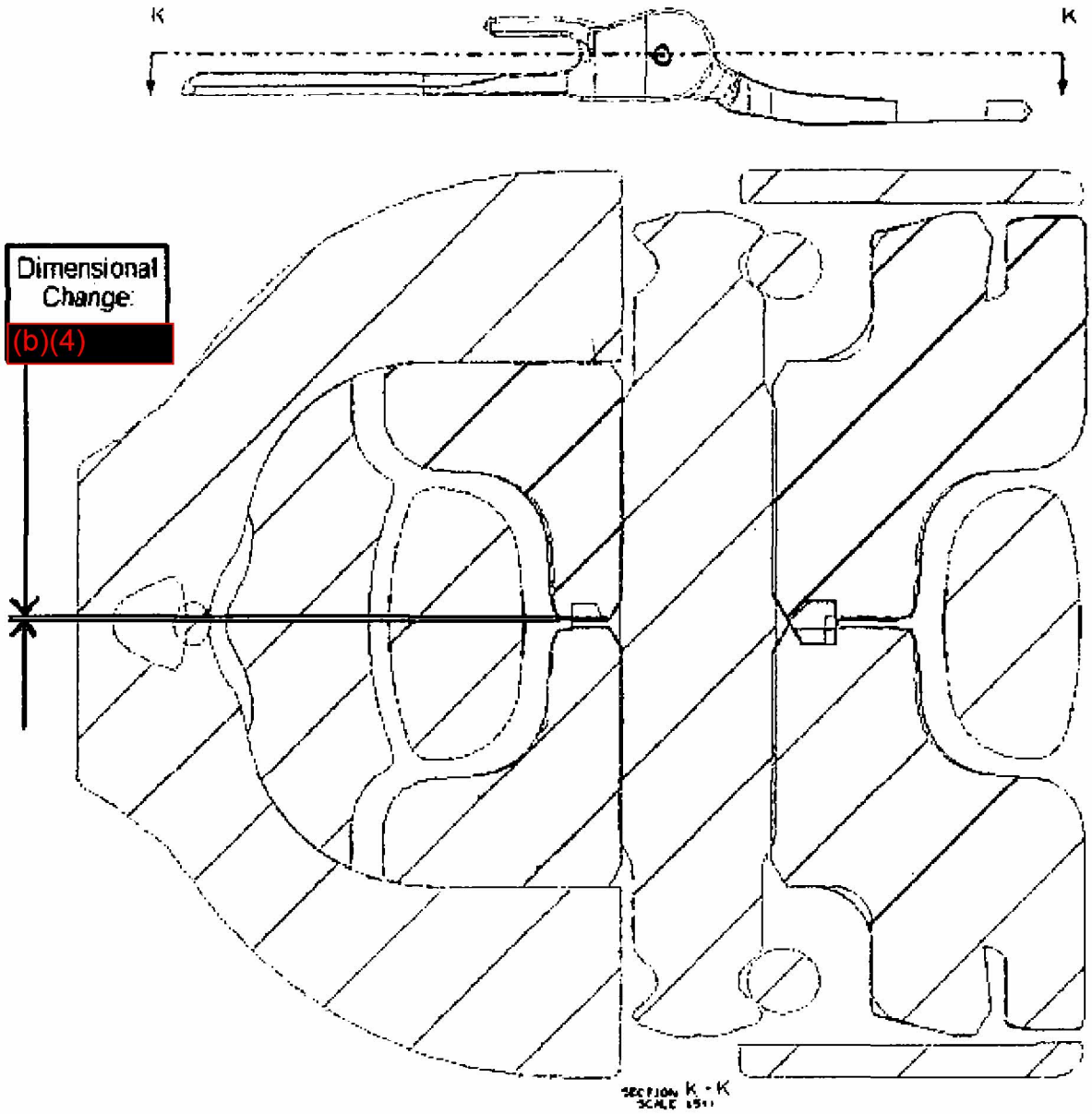

Image 18.8: Wear Testing, Update 4

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Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This update does not affect any articulating surface, and the press-fit of tested assemblies is representative of the current production-intent device.

Wear Testing, Update 5 (Ulnar Bearings-B):
The overall diametric size of the central (shoulder) articulation region of ulnar bearings-B was reduced by (b)(4) in order to ensure the allowable minimum pistoning (proximodistal and anteroposterior translational) motion of the proposed device is no less than that of the predicate device. See Image 18.9 below.

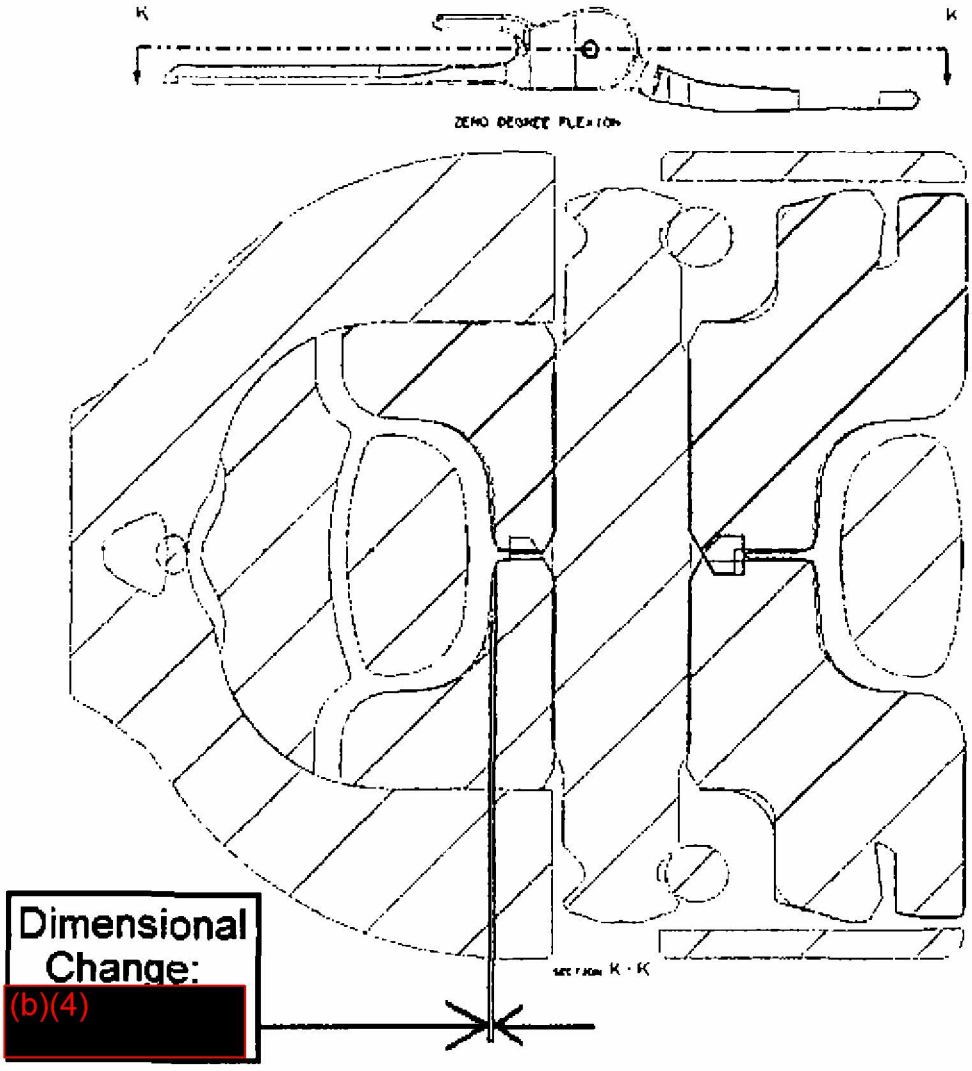

Image 18.9: Wear Testing, Update 5

Questions? Contact FDA/CDRH/OIR/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This slight reduction in the nominal cross-sectional size of the central region of the ulnar bearings-B is numerically negligible with respect to the results and conclusions associated with this test.

Wear Testing, Update 6 (Ulnar Component):
The nitrogen-enrichment process used to increase the hardness of the Zimmer Nexel Total Elbow ulnar component articulating surfaces (the ulnar eye) was changed from Ti-Nidium® (furnace nitriding) to IonGuard® (nitrogen ion implantation).

Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This update is a process change resulting in the same surface hardness and surface roughness specifications, and is therefore numerically negligible with respect to the results and conclusions associated with this test. This rationale is further substantiated by the pin-on-flat wear test conducted (ZRR_WA_2646_12), which concluded that there is no statistical difference between the average weight loss of a VitE HXPE polymer pin sample coupled with a Ti-Nidium® treated disc and a VitE HXPE polymer pin sample coupled with an IonGuard® treated disc.

Wear Testing, Update 7 (Ulnar Component):
On the size 4 and size 5 ulnar implants, approximately (b)(4) of material was removed from the anterior side and approximately (b)(4) of material was added to the posterior side of the neck region (the proximal-most aspect of the ulnar stem, closest to the ulnar eye). Similarly, on the size 6 ulnar implant, approximately (b)(4) of material was removed from the anterior side and approximately (b)(4) of material was added to the posterior side of the neck region. This design change was made to increase the overall flexion-extension range of motion to (b)(or all ulnar-humeral implant combinations. See Image 18.10 below.

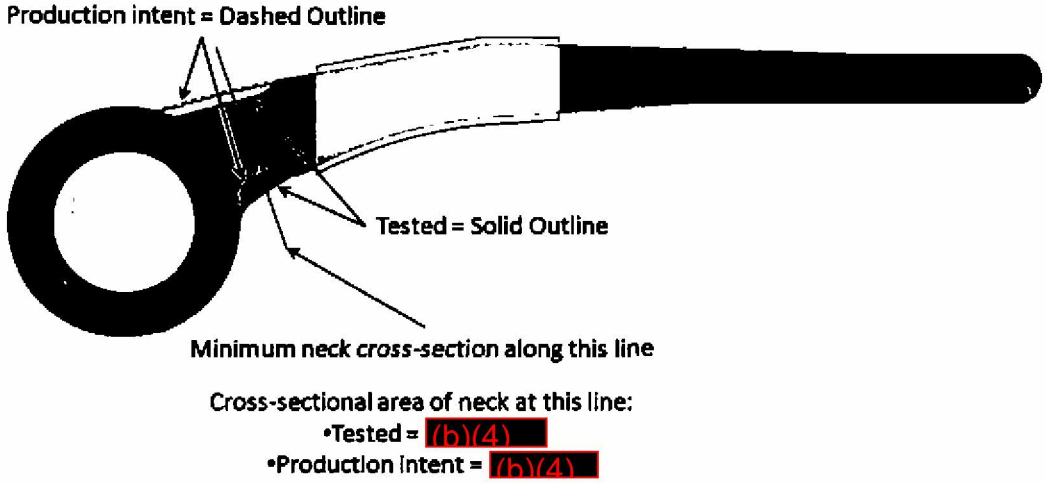

Image 18.10: Wear Testing, Update 7

Questions? Contact FDA/CDRH/OIR/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This change resulted in slightly reduced contact areas on both the medial and lateral faces when in contact with the major internal faces of the ulnar bearings (bearings B and C, as defined in Wear Testing Update 3, above) during Varus/Valgus movements of the ulna relative to the humerus. Because this wear testing was conducted at a fixed varus angle (in order to replicate the clinically-relevant worst-case), only the reduction in contact area on the medial articulation (b)(4) as a result of this update) is relevant. Furthermore, because the majority of wear reported in the results of this testing was produced as a result of the articulation between the ulnar eye and humeral bearing-A (as opposed to the location of the articulation affected by this update), this update is expected to be numerically negligible with respect to the results and conclusions associated with this test. A more detailed explanation of this rationale can be found at the end of ZRR_WA_2552_12.

Internal References

The following research documents, internal to Zimmer, informed this wear testing and are provided for reference in their entirety at the end of this section under:

- Zimmer Research Memo ZRM_WA_0292_11, *Summary of Clinical Complications of the Coonrad/Morrey Elbow System*
- Zimmer Research Report ZRR_WA_2476_11, *Biomechanics Rationale for the Loading of Total Elbow Prosthesis During In Vitro Simulations*
- Zimmer Research Memo ZRM_WA_0193_09, *Development of the Coonrad/Morrey Elbow Durability Test*
- Zimmer Research Memo ZRM_WA_0179_09, *Analysis of Retrieved Coonrad/Morrey Elbow Total Arthroplasty Components*
- Zimmer Research Report ZRR_WA_1988_09, *Literature Review Summary of Elbow Joint Mechanics and Total Elbow Arthroplasty Outcomes*
- Zimmer Research Report ZRR_WA_2338_11, *Vitamin E Highly Crosslinked Polyethylene Shelf Life Study*
- Zimmer Research Report ZRR_WA_2646_12, *Pin-on-Flat Wear Comparison of the New Zimmer Total Elbow and the Coonrad-Morrey Articulation Couples*

Questions? Contact CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Durability Testing

Testing Documentation

- Zimmer Research Memo ZRM_WA_0300_11, *Total Elbow Durability Test Methodology Development*
- Zimmer Research Report ZRR_WA_2542_12, *Durability Testing of Coonrad/Morrey Total Elbow and New Zimmer Total Elbow*

Cumulative Conclusions of Testing Documentation

- The Zimmer Nexel Total Elbow device achieved (b)(4) run-outs at the equivalent of (b)(4) weight-in-hand and (b)(4) varus-valgus moment (b)(4)
- The Zimmer Nexel Total Elbow is at least as safe and effective as the predicate device (Zimmer Coonrad/Morrey Total Elbow) in terms of articular construct durability.
- The Zimmer Nexel Total Elbow is more durable than the predicate device (Zimmer Coonrad/Morrey Total Elbow).

Background

In addition to wear testing the proposed device (the Zimmer Nexel Total Elbow) with a relatively low weight-in-hand and relatively high load frequency (replicating normal activities of daily living), Zimmer conducted an additional (durability) elbow prosthesis performance test to assess resistance to gross mechanical failure under strenuous use (relatively high weights-in-hand at a relatively low frequency of occurrence) conditions.

Due to a lack of durability testing standards specific to the humeroulnar joint, a test was developed by Zimmer, using the predicate device (the Zimmer Coonrad/Morrey Total Elbow), that reproduces clinical complications (such as prosthesis disassembly, severe ulnar and humeral bushing/bearing wear resulting in metal-on-metal articulation and burnishing patterns on the snap/axle-pin components) associated with durability-type failure modes observed on clinically failed and retrieved predicate device assemblies. This test method development can be found in its entirety at the end of this section under Zimmer Research Memo ZRM_WA_0300_11, *Total Elbow Durability Test Methodology Development*.

This durability test was conducted using both the predicate device and the Zimmer Nexel Total Elbow in order to ensure that the proposed device is equal to or better than the predicate device in terms of durability performance. The full test report can be found in at the end of this section under Zimmer Research Report ZRR_WA_2542_12, *Durability Testing of Coonrad/Morrey Total Elbow and New Zimmer Total Elbow*.

Questions should be directed to CDRH/OIR/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Methods
Worst-case size predicate device test specimens were tested under physiologically relevant loading conditions at various load levels at (b)(4) de-ionized water in order to obtain (b)(4) run-outs to (b)(4) cycles at a given load level. The run out load for the predicate device was found to be equivalent to (b)(4) weight-in-hand (b)(4) peak joint reaction force [JRF] and (b)(4) varus-valgus moment).

(b)(4) worst-case size Zimmer Nexel Total Elbow test specimens were then tested under the same conditions at the equivalent of (b)(4) weight-in-hand (b)(4) peak JRF and (b)(4) varus-valgus moment), a load level (b)(higher than the load level at which the predicate device ran out. Additionally, all humeral screws were required to have measureable torque upon removal at the conclusion of testing.

Results
The Zimmer Nexel Total Elbow Humeral Screws did not fracture or exhibit stripping during insertion to the specified minimum and maximum torque values (b)(4) run-outs were obtained at an equivalent o (b)(4) weight-in-hand (a load level one (b)(step higher than the load level at which the C/M Elbow ran out), and there was no evidence of the following durability-type failures prior to or after reaching (b)(4) cycles: metal-on-metal articulation, prosthesis assembly linkage dissociation, fracture of any *component, nor protrusion* of the Humeral screws (screw back-out) from their holes in the Humeral Test Specimens. Additionally, after completion of (b)(4) cycles, the test specimens were able to be completely disassembled and the Humeral Screws had measurable torque during removal.

Device Updates
The following updates were made to the components of the Zimmer Nexel Total Elbow after the conclusion of durability testing and may be considered theoretically relevant to the outcome of the test, but these updates were determined to have no impact on testing results or cumulative conclusions of testing documentation.

Durability Testing, Update 1 (Ulnar Component):
The width of the flat surface on the inner diameter of the ulnar eye increased slightly from (b)(4) (causing an overall inner diameter increase of the ulnar eye by (b)(4) to improve load distribution and ensure the allowable minimum pistoning (proximodistal and anteroposterior translational) motion of the proposed device is no less than that of the predicate device. See Image 18.11 below.

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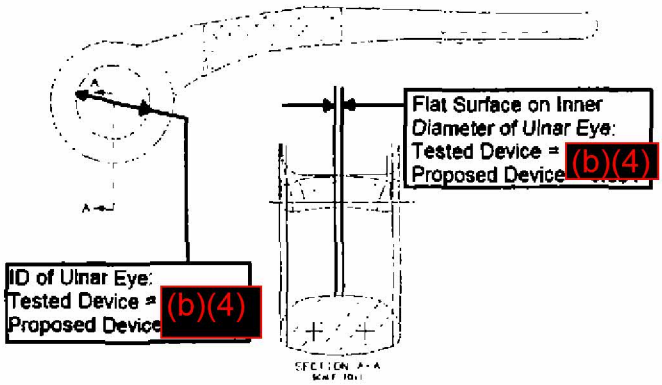

Image 18.11: Durability Testing, Update 1

Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: The slight improvement in load distribution associated with this update is numerically negligible with respect to the results and conclusions associated with this test.

Durability Testing, Update 2 (Ulnar Component):
The mediolateral radial dimension of the ulnar eye was increased by (b)(4)" (causing a decrease of the anteroposterior outer diameter of the ulnar eye by (b)(4)") to improve load distribution. See Image 18.12 below

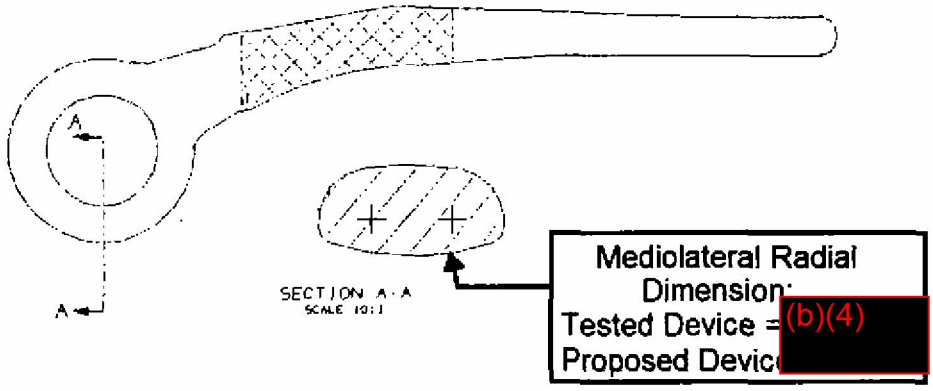

Image 18.12: Durability Testing, Update 2

Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: The slight improvement in load distribution associated with this update is numerically negligible with respect to the results and conclusions associated with this test.

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Durability Testing, Update 3 (Ulnar Bearings-B):
The overall diametric size of the central articulation region of ulnar bearings-B was reduced by (b)(4) in order to ensure the allowable minimum pistoning (proximodistal and anteroposterior translational) motion of the proposed device is no less than that of the predicate device. See Image 18.13 below.

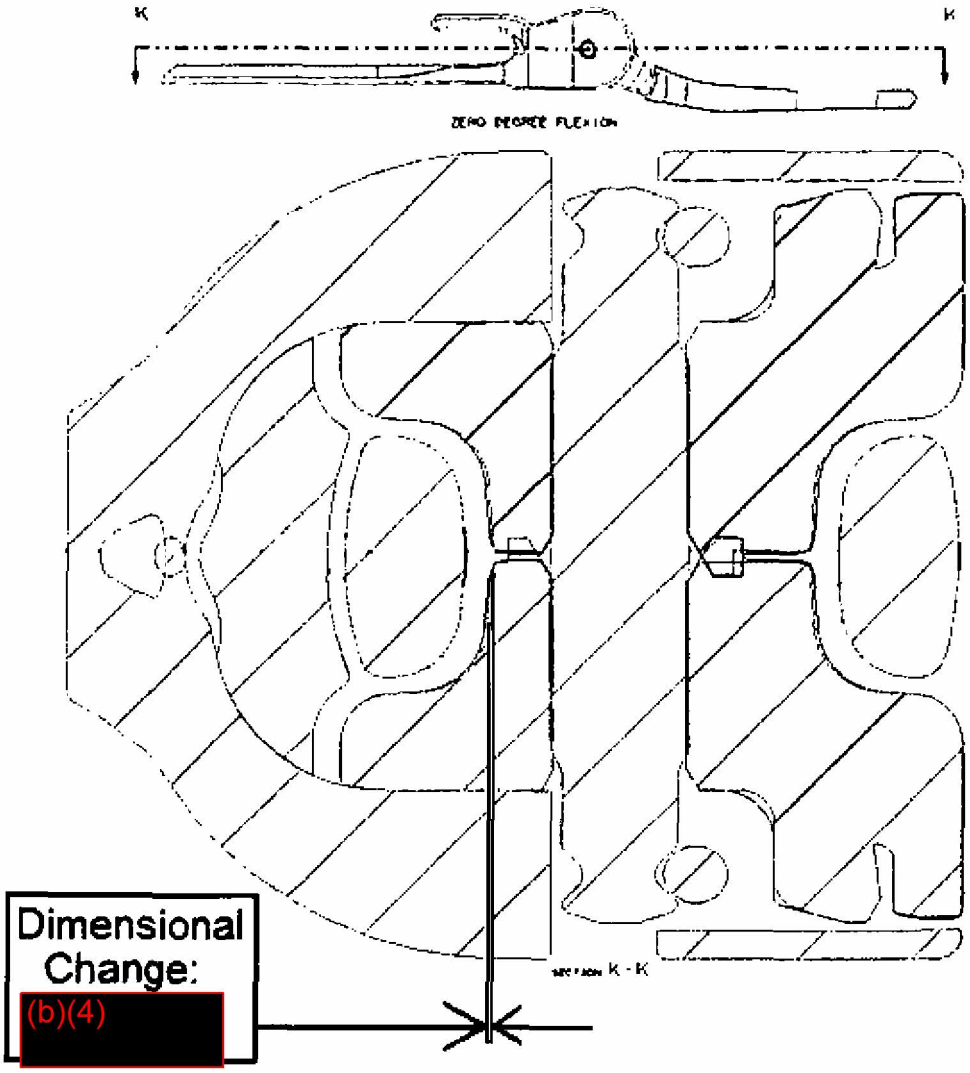

Image 18.13: Durability Testing, Update 3

Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This slight reduction in the nominal cross-sectional size of the central region of the ulnar bearings-B is numerically negligible with respect to the results and conclusions associated with this test.

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Durability Testing, Update 4 (Ulnar Bearings-B):
Slightly modified compound radial geometry on the outer surface (shoulder) of the ulnar bearings-B to ensure proper seating of the bearings within the humeral yoke in all possible tolerance stack-up conditions. See Image 18.14 below.

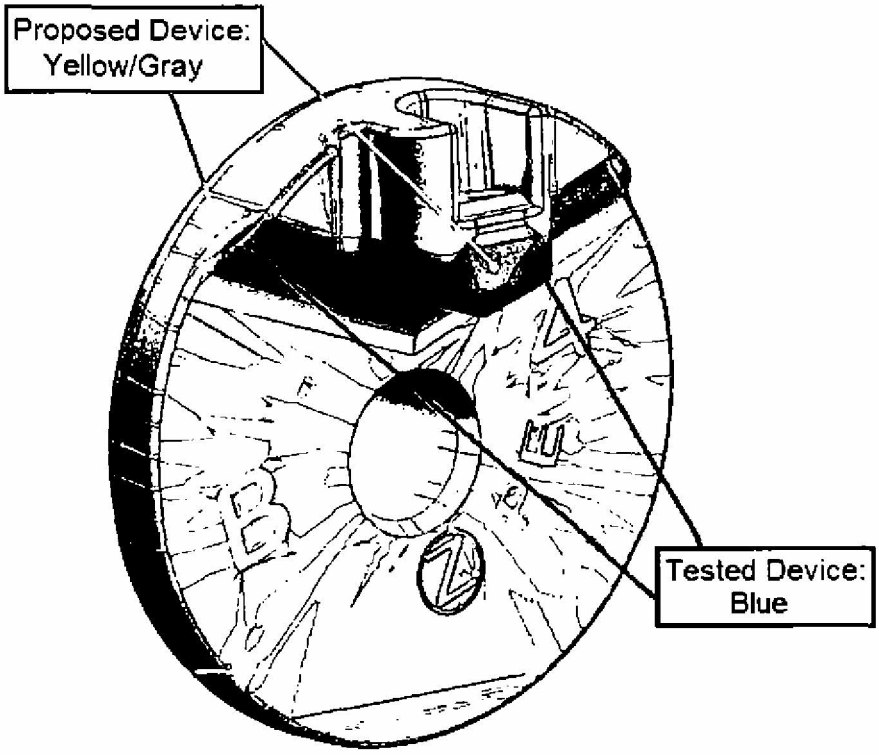

Image 18.14: Durability Testing, Update 4

Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This slight geometrical change is numerically negligible with respect to the results and conclusions associated with this test.

Durability Testing, Update 5 (Ulnar Component):
The nitrogen-enrichment process used to increase the hardness of the Zimmer Nexel Total Elbow ulnar component articulating surfaces (the ulnar eye) was changed from Ti-Nidium® (furnace nitriding) to IonGuard® (nitrogen ion implantation).

Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This update is a process change resulting in the same surface hardness and surface roughness specifications, and is therefore numerically negligible with respect to the results and conclusions associated with this test.

Questions? Contact BA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Durability Testing, Update 6 (Ulnar Component)
On the size 4 and size 5 ulnar implants, approximately (b)(4) of material was removed from the anterior side and approximately (b)(4) of material was added to the posterior side of the neck region (the proximal-most aspect of the ulnar stem, closest to the ulnar eye). Similarly, on the size 6 ulnar implant, approximately (b)(4) of material was removed from the anterior side and approximately (b)(4) of material was added to the posterior side of the neck region. This design change was made to increase the overall flexion-extension range of motion to (b)(for all ulnar-humeral implant combinations. See Image 18.15 below.

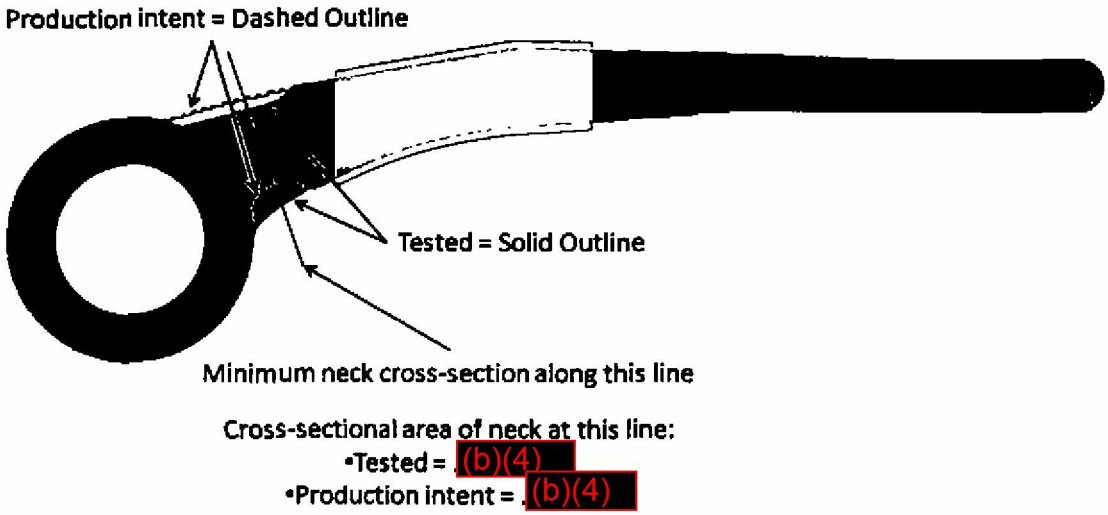

Image 18.15: Durability Testing, Update 6

Rationale for why this update does not change testing results or cumulative conclusions of testing documentation: This change reduced the lateral articulation contact area from (b)(4) to (b)(4) and reduced the medial articulation contact area from (b)(4); these two areas articulate on the major internal faces of the ulnar bearings (bearings B and C, as defined in Wear Testing Update 3, above) during Varus/Valgus movements of the ulna relative to the humerus. Given the fact that this change in the outermost contact surfaces of the ulnar articulation is slight, compounded with the fact that the central and medial/lateral contoured surfaces of the ulnar eye carry and distribute the vast majority of the loading onto the apposing articulating surfaces of the ulnar bearings B (as opposed to the outermost contact surfaces affected by this change), this update is expected to be numerically negligible with respect to the results and conclusions associated with this test.

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Internal References

The following research documents, internal to Zimmer, informed this durability testing and are provided for reference in their entirety at the end of this section under:

- Zimmer Research Memo ZRM_WA_0292_11, *Summary of Clinical Complications of the Coonrad/Morrey Elbow System*
- Zimmer Research Report ZRR_WA_2476_11, *Biomechanics Rationale for the Loading of Total Elbow Prosthesis During In Vitro Simulations*
- Zimmer Research Memo ZRM_WA_0179_09, *Analysis of Retrieved Coonrad/Morrey Elbow Total Arthroplasty Components*
- Zimmer Research Report ZRR_WA_1988_09, *Literature Review Summary of Elbow Joint Mechanics and Total Elbow Arthroplasty Outcomes*
- Zimmer Research Report ZRR_WI_2441_11, *Finite Element Analysis of the Coonrad-Morrey Total Elbow System*
- Zimmer Research Report ZRR_WA_2338_11, *Vitamin E Highly Crosslinked Polyethylene Shelf Life Study*

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Modular Connection Fatigue Testing

Testing Documentation
Zimmer Research Report ZRR_WA_2598_12, *New Zimmer Total Elbow Prosthesis Modular Connection Fatigue Testing*

Cumulative Conclusions of Testing Documentation

- The Zimmer Nexel Total Elbow is safe and effective in terms of non-articulating, mechanically locked, modular connection fatigue.
- The median fatigue strength of the non-articulating, mechanically locked, modular Zimmer Nexel Total Elbow implant components was no less than (b)(4).

Background
Modular junctions have an inherent risk of adverse events that have the potential to compromise the system fatigue strength resulting from loosening, micromotion, fretting and galvanic corrosion due to contact of dissimilar materials.

Because the predicate device (the Zimmer Coonrad/Morrey Total Elbow) does not have non-articulating, mechanically-locked, modular implant components comparable to those of the proposed device (the Zimmer Nexel Total Elbow), side-by-side testing comparing the predicate device to the proposed device was irrelevant. Instead, testing recommended in the Draft FDA Guidance Document dated 1 May 1995 and entitled *Guidance Document for Testing Non-Articulating, "Mechanically Locked", Modular Implant Components* was conducted to provide reasonable assurance of safety and effectiveness of the Zimmer Nexel Total Elbow in terms of modular connection fatigue.

The loading level for this test was derived from the median proximal (plasma spray region) fatigue strength of the predicate device ulnar stem.

Methods
(b)(4) worst-case size Zimmer Nexel Total Elbow non-articulating, mechanically locked, modular connections were subjected to cyclic loading under worst-case physiologic conditions for (b)(4). Testing was conducted at a frequency of (b)(4) in a Ringer's solution maintained at (b)(4) and a pH (b)(4). In addition to reporting mean system mass loss of the modular connection, occurrence (or non-occurrence) of the following three key failure modes commonly associated with modular connections were recorded: component fracture, component disassociation and lack of measurable screw torque (i.e. screw back-out).

Results
The median fatigue strength of the non-articulating, mechanically locked, modular Zimmer Nexel Total Elbow implant components was no less than (b)(4). No components fractured or disassociated prior to the end of the test; and, all humeral

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screws had measureable torque upon removal at the conclusion of testing. The mean system mass loss of the loaded and soak-control Zimmer Nexel Total Elbow specimens was (b)(4) , respectively.

Internal References

The following research documents, internal to Zimmer, informed this modular connection fatigue testing and are provided for reference in their entirety at the end of this section under:

- Zimmer Research Memo ZRM_WA_0292_11, *Summary of Clinical Complications of the Coonrad/Morrey Elbow System*
- Zimmer Research Report ZRR_WA_2476_11, *Biomechanics Rationale for the Loading of Total Elbow Prosthesis During In Vitro Simulations*
- Zimmer Research Report ZRR_WA_1988_09, *Literature Review Summary of Elbow Joint Mechanics and Total Elbow Arthroplasty Outcomes*
- Zimmer Research Report ZRR_WA_2481_11, *Determination of the Functional Torque Range of the New Zimmer Total Elbow Humeral Screw and Hex Driver*
- Memo to DHF File Z07-014, *Rationale for Determination of Torque Specification and Torque Range Requirement for the Mechanical Fastening Used in Zimmer New Total Elbow Prosthesis*
- Zimmer Research Report ZRR_WA_2252_10, *Evaluation of the AS/BF Taper Adaptor Component Using Electrochemical Test Methods*

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Bench Testing in support of Vivacit-E Claim

Proposed Claim

Vivacit-E Vitamin E Highly Crosslinked Polyethylene exhibits improved delamination resistance compared to conventional polyethylene under aged conditions (per ASTM F2003). The results of *in vitro* delamination tests have not been shown to correlate with clinical delamination mechanisms.

Evidence to Support Claim

(b)(4)

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The above claim is supported by the following references:

[1]. ZRR_WA_2580_12, Evaluation of the Delamination Resistance of *Vivacit-E*™ Ultra High Molecular Weight Polyethylene.

[2]. Goldberg SH, Urban RM, Jacobs JJ, et al. Modes of Wear After Semiconstrained Total Elbow Arthroplasty. J Bone Joint Surg Am. 2008; 90:609-619.

[3]. Carol J. Bell, Peter S. Walker, Melanie R. Abeysundera et al. Effect of oxidation on delamination of ultrahigh-molecular-weight polyethylene tibial components. **J Arthroplasty**. 1998; 13, Issue 3: 280-290

[4]. ZRR_WA_2409_11, Extended Aging of Vitamin E Highly Crosslinked Polyethylene (Master File volume 2, page 394).

[5]. ZRR_WA_2399_11_REV1, Effect of Prolonged Aging on the Wear Performance of Vitamin E IT Liner. (Testing from predicate *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene Liners 510(k) submission K120370.)

[6]. TM1267, Delamination Sub-Surface Fatigue Wear Test of Electron-Beam Crosslinked Polyethylene (Testing from *Prolong* Delamination Claim Special 510(k) submission K013991).

[7]. D'Lima DD, Steklov N, Fregly B, et al. In Vivo Contact Stresses During Activities of Daily Living After Knee Arthroplasty. J Orthop Res 26:1549-1555 (2008).

[8]. ZRR_WI_1222_12, Finite Element Analyses of the new Zimmer Total Elbow.

Questions? Contact CDRH/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Zimmer Research Report

(b)(4)

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