Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

K110397
p1/2

510(k) Summary

AUG 16 2011

Applicant / Sponsor:	DePuy Orthopaedics Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration No.: 1818910
Contact Person:	Nancy S. Friddle Project Manager, Regulatory Affairs Tel: (574) 371-4923 Fax: (574) 371-4987
Proprietary Name:	TruMatch™ Personalized Solutions
Common Name:	Total Knee Prosthesis
Classification Name:	21 CFR 888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. Class II
Product Code:	JWH
Subsequent Product Code:	OOG

Device Description:

Subject of this premarket notification are TruMatch™ Patient Specific Instruments which are designed and manufactured from patient imaging data and used with other DePuy Orthopaedics implants.

Indications and Intended Use:

The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The anatomical landmarks necessary for the creation of the TruMatch™ Patient Specific Instruments must be present and identifiable on CT.

The TruMatch™ Patient Specific Instruments are intended for use with Sigma® Total Knee Implants and Attune™ Total Knee Implants and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only.

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

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Summary of Technologies/Substantial Equivalence:

The TruMatch™ Patient Specific Instruments have the same indications, intended use, similar design and are substantially equivalent to the Smith & Nephew's Patient Matched Cutting Blocks and also to the traditional instruments that are associated with the Sigma® and Attune™ cleared knee implant systems. The TruMatch™ Patient Specific Instruments are used in conjunction with the DePuy Orthopaedics, Inc Sigma and Attune implant systems identified in the table below.

System	510k	Clearance Date
Sigma Total Knee System	K882234	10/20/1988
	K884796	3/29/1989
	K943462	12/21/1994
	K950010	5/15/1995
	K944538	9/26/1995
	K961685	7/10/1996
	K961685	7/10/1996
	K971189	7/17/1997
	K971189	7/17/1997
	K082500	11/18/2008
Attune Total Knee System	K101433	12/10/2010

Non-Clinical Testing:

The following testing was performed to demonstrate the substantial equivalence of the TruMatch™ Patient Specific Instruments to the predicate devices.

- TruMatch™ Dimensional Stability Test
- Cadaver Accuracy Study
- Design Process and Design Software Repeatability Study
- Software Validation and Verification Summary

The tests results demonstrate that all acceptance criteria were met.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the TruMatch™ Patient Specific Instruments and the predicate devices.

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

DePuy Orthopaedics, Inc.
% Ms. Nancy S. Friddle
Project Manager, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

AUG 16 2011

Re: K110397
Trade/Device Name: DePuy TruMatch™ Patient Specific Instruments
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, OOG
Dated: June 15, 2011
Received: June 16, 2011

Dear Ms. Friddle:

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 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 # 2016-626; Released by CDRH on 11-01-2016

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
Director
Division of Surgical, Orthopedic,
and Restorative 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 # 2016-626; Released by CDRH on 11-01-2016

K110397

2. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: DePuy TruMatch™ Patient Specific Instruments

Indications for Use:

The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The anatomical landmarks necessary for the creation of the TruMatch™ Patient Specific Instruments must be present and identifiable on CT.

The TruMatch™ Patient Specific Instruments are intended for use with Sigma® Total Knee Implants and Attune™ Total Knee Implants and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110397

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

DePuy Orthopaedics, Inc.
% Ms. Nancy S. Friddle
Project Manager, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

AUG 16 2011

Re: K110397
Trade/Device Name: DePuy TruMatch™ Patient Specific Instruments
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, OOG
Dated: June 15, 2011
Received: June 16, 2011

Dear Ms. Friddle:

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 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 # 2016-626; Released by CDRH on 11-01-2016

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
Director
Division of Surgical, Orthopedic,
and Restorative 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 # 2016-626; Released by CDRH on 11-01-2016

K110397

2. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: DePuy TruMatch™ Patient Specific Instruments

Indications for Use:

The TruMatch™ Patient Specific Instruments are intended to be used as patient specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The anatomical landmarks necessary for the creation of the TruMatch™ Patient Specific Instruments must be present and identifiable on CT.

The TruMatch™ Patient Specific Instruments are intended for use with Sigma® Total Knee Implants and Attune™ Total Knee Implants and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110397

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

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

June 16, 2011

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DRIVE
WARSAW, INDIANA 46581-0988
ATTN: NANCY S. FRIDDLE

510k Number: K110397

Product: TRUMATCH PERSONALIZED

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: 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).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

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.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k 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 # 2016-626; Released by CDRH on 11-01-2016

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

June 03, 2011

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DRIVE
WARSAW, INDIANA 46581-0988
ATTN: NANCY S. FRIDDLE

510k Number: K110397
Product: TRUMATCH PERSONALIZED SOLUTION

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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

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Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

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

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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

March 24, 2011

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DRIVE
WARSAW, INDIANA 46581-0988
ATTN: NANCY S. FRIDDLE

510k Number: K110397

Product: TRUMATCH PERSONALIZED

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: 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).

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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.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k 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 # 2016-626; Released by CDRH on 11-01-2016

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

February 25, 2011

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DRIVE
WARSAW, INDIANA 46581-0988
ATTN: NANCY S. FRIDDLE

510k Number: K110397
Product: TRUMATCH PERSONALIZED SOLUTION

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

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

February 14, 2011

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DRIVE
WARSAW, INDIANA 46581-0988
ATTN: NANCY S. FRIDDLE

510k Number: K110397
Received: 2/11/2011
Product: TRUMATCH PERSONALIZED SOLUTION

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

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 # 2016-626; Released by CDRH on 11-01-2016

K110397

DePuy
a Johnson-Johnson company

February 10, 2011

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

FDA CDRH DMC
FEB 11 2011
Received
K2

RE: Traditional 510(k) - DePuy TruMatch™ Patient Specific Instruments

Dear Madam/Sir:

DePuy Orthopaedics, Inc. submits the enclosed documentation in duplicate (one paper and one exact duplicate CD) on the DePuy TruMatch™ Patient Specific Instruments as a **Traditional 510(k)**. The basis for this submission is that these are patient specific instruments for use in total knee replacement surgery.

DePuy certifies that the .pdf file provided on the accompanying CD is an exact duplicate of the paper copy of this premarket notification submission.

The following regulation, product codes and classifications are recommended for this device:

Classification Regulation:	888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Class:	II
Panel:	87 (Orthopedic Devices)
Product Codes:	JWH – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Pursuant to 21 CFR 807.95(c) (3), DePuy considers this 510(k) submission to be confidential commercial information and requests that FDA treats it as such. DePuy has taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Thank you in advance for your consideration of this submission. If there are any questions, please feel free to contact me by phone at (574) 371-4923 or by email at nfriddle@its.jnj.com. Alternatively, in my absence, please feel free to contact Janet Johnson at (574) 372-7469 or by email at jjohns70@its.jnj.com.

Sincerely,

Nancy Friddle

Nancy Friddle
Project Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

DePuy
a Johnson-Johnson company

TRADITIONAL 510(K)
PREMARKET NOTIFICATION

DEPUY TRUMATCH™ PATIENT SPECIFIC INSTRUMENTS

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

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Form Approved: OMB No. 0910-511. 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)

DEPUY ORTHOPAEDICS INC
PO Box 988
700 Orthopaedic Drive
Warsaw IN 46581
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****3282

2. CONTACT NAME
Kathy Boggs

2.1 E-MAIL ADDRESS
kboggs2@its.jnj.com

2.2 TELEPHONE NUMBER (include Area code)
574-371-4945

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
574-372-4987

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) 03-Feb-2011

Form FDA 3601 (01/2007)

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

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February 10, 2011

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

RE: Traditional 510(k) - DePuy TruMatch™ Patient Specific Instruments

Dear Madam/Sir:

DePuy Orthopaedics, Inc. submits the enclosed documentation in duplicate (one paper and one exact duplicate CD) on the DePuy TruMatch™ Patient Specific Instruments as a **Traditional 510(k)**. The basis for this submission is that these are patient specific instruments for use in total knee replacement surgery.

DePuy certifies that the .pdf file provided on the accompanying CD is an exact duplicate of the paper copy of this premarket notification submission.

The following regulation, product codes and classifications are recommended for this device:

Classification Regulation:	888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Class:	II
Panel:	87 (Orthopedic Devices)
Product Codes:	JWH – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Pursuant to 21 CFR 807.95(c) (3), DePuy considers this 510(k) submission to be confidential commercial information and requests that FDA treats it as such. DePuy has taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Thank you in advance for your consideration of this submission. If there are any questions, please feel free to contact me by phone at (574) 371-4923 or by email at nfriddle@its.jnj.com. Alternatively, in my absence, please feel free to contact Janet Johnson at (574) 372-7469 or by email at jjohns70@its.jnj.com.

Sincerely,

Nancy Friddle

Nancy Friddle
Project Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.

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

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TABLE 1: DESIGN AND USE OF THE DEVICES

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?[A]	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?[A]		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

[A] A device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes.

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2. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: DePuy TruMatch™ Patient Specific Instruments

Indications for Use:

The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The TruMatch™ Patient Specific Instruments are intended for use with existing DePuy Orthopaedics, Inc. knee systems and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 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-IDESTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary

Applicant / Sponsor:	DePuy Orthopaedics Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration No.: 1818910
Contact Person:	Nancy S. Friddle Project Manager, Regulatory Affairs Tel: (574) 371-4923 Fax: (574) 371-4987
Proprietary Name:	TruMatch™ Personalized Solutions
Common Name:	Total Knee Prosthesis
Classification Name**:**	21 CFR 888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. Class II
Product Code:	JWH

Device Description:

Subject of this premarket notification are TruMatch™ Patient Specific Instruments which are designed and manufactured from patient imaging data and used with other DePuy Orthopaedics implants.

Indications and Intended Use:

The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The TruMatch™ Patient Specific Instruments are intended for use with existing DePuy Orthopaedics, Inc. knee systems and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only.

Summary of Technologies/Substantial Equivalence:

The TruMatch™ Patient Specific Instruments have the same indications, intended use, similar design and are substantially equivalent to the Smith & Nephew's Patient Matched Cutting Blocks. The TruMatch™ Patient Specific Instruments are used in conjunction with the DePuy Orthopaedics, Inc implant systems identified in the table below.

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

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System	510k	Clearance Date
Sigma Total Knee System	K882234	10/20/1988
	K884796	3/29/1989
	K943462	12/21/1994
	K950010	5/15/1995
	K944538	9/26/1995
	K961685	7/10/1996
	K961685	7/10/1996
	K971189	7/17/1997
	K971189	7/17/1997
	K082500	11/18/2008
Attune Total Knee System	K101433	12/10/2010

Non-Clinical Testing:

The following testing was performed to demonstrate the substantial equivalence of the TruMatch™ Patient Specific Instruments to the predicate devices.

- TruMatch™ Dimensional Stability Test
- Cadaver Accuracy Study
- Design Process and Design Software Repeatability Study
- Software Validation and Verification Summary

The tests results demonstrate that all acceptance criteria were met.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the TruMatch™ Patient Specific Instruments and the predicate devices.

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

4. TRUTHFUL AND ACCURACY STATEMENT

In accordance with 21 CFR §807.87 (k), I believe to the best of my knowledge, that all the data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6) [redacted]

Sr. Project Engineer, TruMatch™ Development
DePuy Orthopaedics, Inc.

TruMatch™ Patient Specific Instruments
Date: February 10, 2011

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

5. CLASS III SUMMARY AND CERTIFICATION

N/A This is a Class II device.

6. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

N/A. Clinical testing was not necessary to determine the substantial equivalence of the TruMatch™ Patient Specific Instruments to the predicate devices.

7. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

N/A. Declarations of Conformity and Summary Reports are not required for Traditional 510(k) premarket notifications.

8. EXECUTIVE SUMMARY

Device Description:

The TruMatch™ Patient Specific Instruments are single-use instruments that are preoperatively designed to assist in the positioning of the distal femoral and proximal tibial cuts for a particular patient. TruMatch™ Patient Specific Instrument sets include a proximal tibial and distal femoral instrument. (b)(4) fit onto the patient's bone (b)(4).

TruMatch™ patient specific instruments have two variants: cutting guides and pin guides. TruMatch™ cutting guides include an integrated stainless steel saw capture and drill bushings and bone cuts can be made in a single step using the integrated stainless steel saw capture. TruMatch™ pin guides include modular stainless steel saw captures and drill bushings and bone cuts are made in two steps. First pins are placed with the TruMatch™ pin guide and drill bushings, and then second, a modular saw capture is assembled over the pins and bone cuts are made.

TruMatch™ Patient Specific Instruments are manufactured from RenShape® and stainless steel which are strong and biocompatible materials. Stainless steel saw captures and drill bushings produce accurate bone cuts and drill holes.

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Indications and Intended Use:

The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The TruMatch™ Patient Specific Instruments are intended for use with existing DePuy Orthopaedics, Inc. knee systems and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only.

Predicate Devices:

- Smith & Nephew Patient Matched Cutting Blocks, K082358

The TruMatch™ Patient Specific Instruments have the same indications, intended use, design and are substantially equivalent to the Smith & Nephew's Patient Matched Cutting Blocks. The following testing was performed to demonstrate the substantial equivalence of the TruMatch™ Patient Specific Instruments to the predicate devices.

- TruMatch™ Dimensional Stability Test
- Cadaver Accuracy Study
- Design Process and Design Software Repeatability Study
- Software Validation and Verification Summary

The tests results demonstrate that all acceptance criteria were met.

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

9. DEVICE DESCRIPTION

The TruMatch™ Patient Specific Instruments are single-use instruments that are preoperatively designed to assist in the positioning of the distal femoral and proximal tibial cuts for a particular patient. A TruMatch™ Patient Specific Instrument set includes a proximal tibial and distal femoral instrument. (b)(4) , and fit onto the patient's bone(b)(4) .

TruMatch™ Patient Specific Instruments have two variants: cutting guides and pin guides. TruMatch™ cutting guides include an integrated stainless steel saw capture and drill bushings. Bone cuts can be made in a single step using the integrated stainless steel saw capture. TruMatch™ pin guides include modular stainless steel saw captures and drill bushings and bone cuts are made in two steps. First pins are placed with the TruMatch™ pin guides and drill bushings, and then second, a modular saw capture is assembled over the pins and bone cuts are made. During surgery, after initial cuts or pin placements with the TruMatch™ Patient Specific Instruments are made, standard instruments and provisionals (trials) are used to complete the surgery.

TruMatch™ Patient Specific Instruments are manufactured from RenShape®(b)(4) (b)(4) and stainless steel which are strong and biocompatible materials. Stainless steel saw captures and drill bushings are used to produce accurate bone cuts and drill holes.

The TruMatch™ Patient Specific Instruments are designed to be used with Sigma Fixed Bearing Implants and the Attune Total Knee Implants:

1. Sigma CR Femoral components
2. Sigma CR150 Femoral components:
3. Sigma PS Femoral components
4. Sigma Standard FB Tibial Trays:
5. Sigma Modular FB Tibial Tray
6. Sigma Modular Plus FB Tibial Tray
7. Sigma Fixed Bearing Stabilized Inserts
8. Sigma Fixed Bearing Curved Inserts
9. Sigma Fixed Bearing PLI Inserts
10. Sigma Cruciate Retaining All Poly Tibia
11. Sigma Cruciate Retaining Posterior Lipped All Poly Tibia
12. Sigma Cruciate-Subsitituting All Poly Tibia
13. Attune Total Knee Implants

Following is a detailed description of the process for TruMatch™ Patient Specific Instruments:

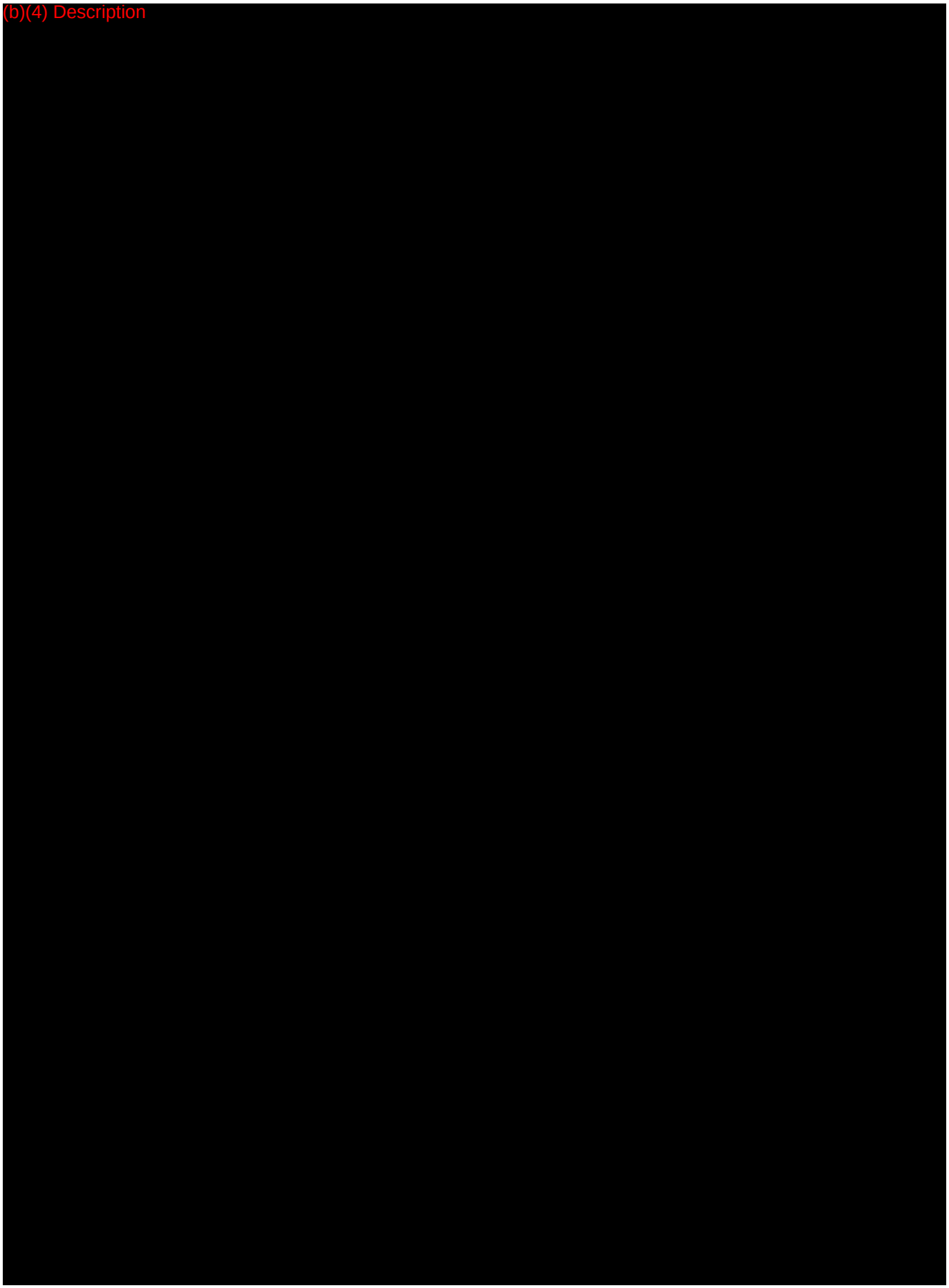
Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

The TruMatch™ process has 13 steps and it begins when a surgeon registers for TruMatch™ by providing his or her surgical preferences. Each of the 13 steps is listed below and then described in detail.

Step	Description	Owner
(b)(4) Description		

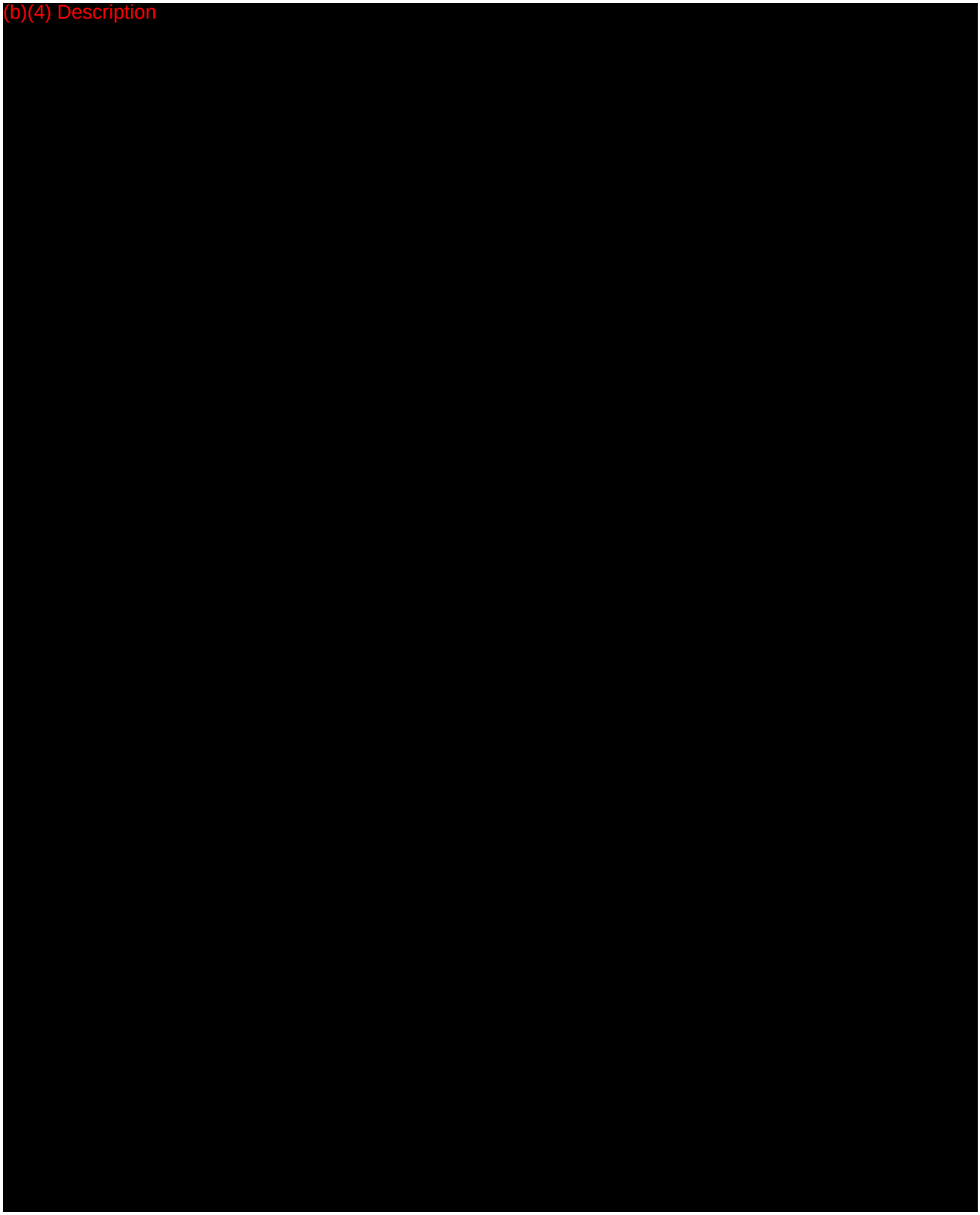
Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4) Description



Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4) Description



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10. SUBSTANTIAL EQUIVALENCE DISCUSSION

PREDICATE DEVICES:

- Smith & Nephew Patient Matched Cutting Blocks, K082358

The design of the TruMatch™ Patient Specific Instruments is substantially equivalent to the Smith & Nephew Patient Match Cutting Blocks (K082358). Both instruments utilize cutting saw captures and drill bushings that help orient bone saws that are used to prepare the distal femur and proximal tibia for total knee replacement. The TruMatch™ Patient Specific Instruments and Smith & Nephew Patient Match Cutting Blocks, although generated using different imaging data (CT vs. MRI and X-ray), have a similar shape, function, intended use and indications for use as further described in Table 1 & 2 below.

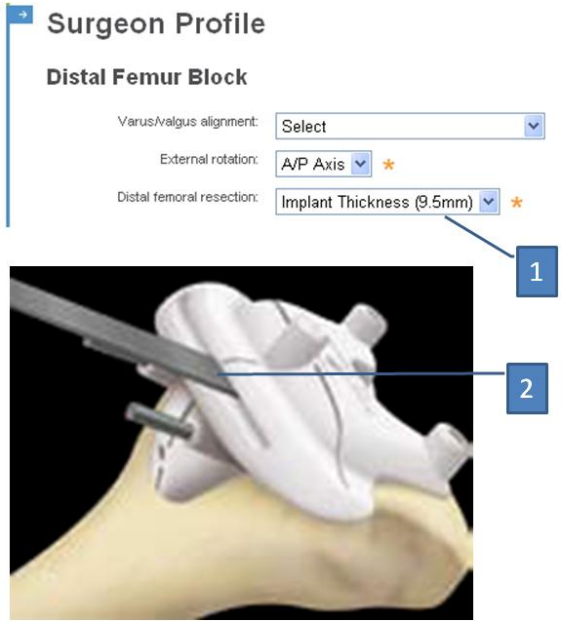
Comparisons of the TruMatch™ Patient Specific Instruments and the predicate devices are provided in Tables 1 through 3 below.

Table 1: Comparison of TruMatch™ Patient Specific Instruments and Smith & Nephew Patient Matched Cutting Blocks

	TruMatch™ Patient Specific Instrumentation	**DePuy's HP (standard) Cutting Blocks**	**Smith & Nephew's Patient Matched Cutting Blocks (K082358)**
Intended Use/ Indications for use	Patient-specific surgical instrumentation to assist in the positioning of joint replacement components intra-operatively and in guiding the marking of bone before cutting.	Surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting.	Patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting.
Compatibility	For use with Sigma and Attune Knee Implants.	For use with Sigma Knee Implants.	For use with S&N Knee Implants.
Use	Single use	Reusable	Single use
Sterilization	(b)(4)	Non-Sterile (to be autoclaved)	Sterile
Design	Based on CT scan	No imaging	Based on MRI + Long film x-ray
Size	Patient Specific	One size	Patient Specific
Materials	Renshape & Stainless Steel	Stainless Steel	Nylon

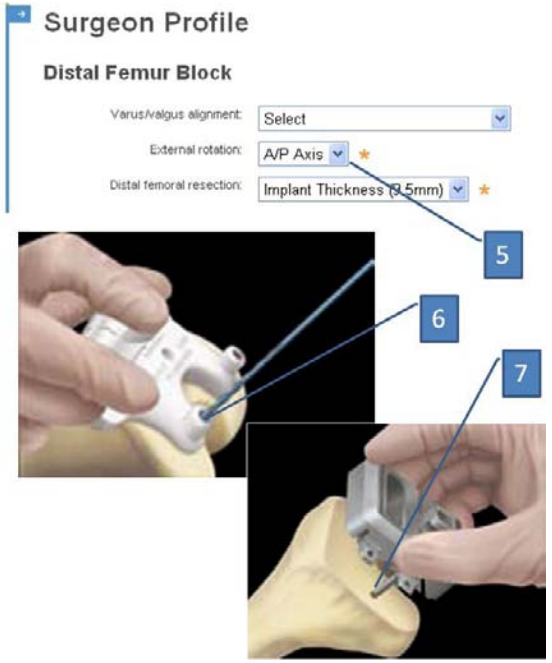
Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Table 2: Comparison of TruMatch™ Patient Specific Instruments and Smith & Nephew Patient Matched Cutting Blocks

	TruMatch™ Cutting Blocks	**Smith and Nephew Patient Matched Cutting Blocks (K082358)**
Implant Sizing	CT scan and Patient Proposal	X-Ray, MRI, and Patient Proposal
Femoral Resection Level	Surgeon Preference – Planned using long leg CT scan, Surgeon Input, and Patient Proposal; then built into cutting block. Illustrated below is the TruMatch™ (b)(4) [redacted] Also illustrated is the TruMatch™ femoral cutting block (b)(4) [redacted] The TruMatch™ cutting slot is (b)(4) thick and manufactured from (b) stainless steel. (b)(4) [redacted]	Surgeon Preference – Planned using MRI scan, long leg X-Ray, Surgeon Input, and Patient Proposal; then built into cutting block. Illustrated below is the Smith & Nephew Patient Matched website where the surgeon has inputted preferences for a femoral resection level of 9.5 mm (flag 1). Also illustrated is the Smith & Nephew cutting block positioned to deliver a 9.5 mm distal resection (flag 2). The Smith and Nephew cutting slot is approximately 1.4 mm thick and manufactured from Nylon. 

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Tibial Resection Level	Surgeon Preference – Planned using long leg CT scan, Surgeon Input, and (b)(4); then built into cutting block. Illustrated below is the TruMatch™ (b)(4) Also illustrated is the TruMatch™ tibial cutting block (b)(4) The TruMatch™ cutting slot is (b)(4) mm thick and manufactured from (b) stainless steel. (b)(4)	Surgeon Preference – Planned using MRI scan, long leg X-Ray, Surgeon Input, and Patient Proposal; then built into cutting block. Illustrated below is the Smith and Nephew Patient Matched website where the surgeon can input a preference for a tibial resection level (flag 3). Also illustrated is the Smith and Nephew tibial cutting block positioned to deliver the requested tibial resection (flag 4). The Smith and Nephew cutting slot is approximately 1.4 mm thick and manufactured from Nylon. 
Femoral Rotation	Surgeon Preference – Planned using CT scan, surgeon input, and Patient Proposal; then built into cutting block. Illustrated below is the TruMatch™ (b)(4)	Surgeon Preference – Planned using MRI scan, X-Ray, Surgeon Input, and Patient Proposal; then built into cutting block. Illustrated below is the Smith and Nephew Patient Matched website where the surgeon has inputted a preference for femoral

	(b)(4) Also illustrated is the TruMatch™ femoral cutting block (b)(4) Flag 7 illustrates the femoral finishing block which is (b)(4) (b)(4)	rotation aligned to the AP axis (flag 5). Also illustrated is the Smith and Nephew Patient Matched femoral cutting block with distal drill bushings positioned to deliver femoral rotation aligned to the AP axis (flag 6). Flag 7 illustrates the femoral finishing block which is placed using the two previously drilled holes and used to guide a saw to finish the femoral bone cuts. 
Tibial Slope	Surgeon Preference – Planned using CT scan (b)(4) (b)(4) ; then built into cutting block	Surgeon Preference –Planned using MRI scan, X-Ray, Surgeon Input, and Patient Proposal; then built into cutting block.
Leg Alignment	Mechanical axis and Surgeon Preference – Planned using long leg CT scan (b)(4) ; then built into cutting block	Mechanical Axis and Surgeon Preference –Planned using MRI scan, long leg X-Ray, Surgeon Input, and Patient Proposal; then built into cutting block.

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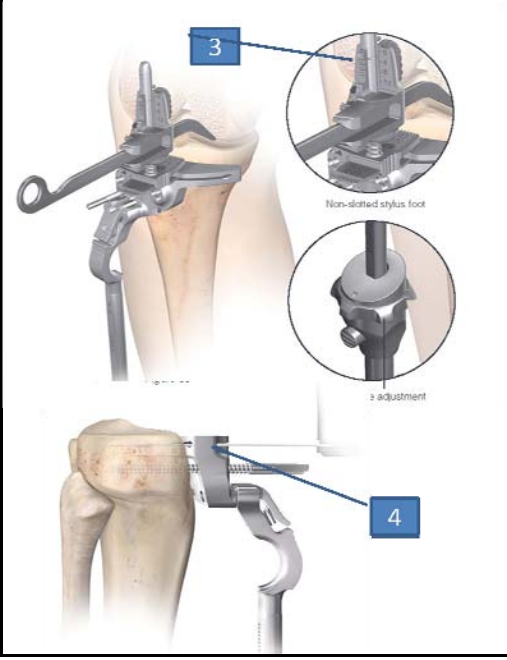
Alignment Verification	Verified with HP alignment rod.	Verified with the Smith and Nephew "alignment checker."
Alignment Options	Selected by the surgeon via the TruMatch™ (b)(4) Surgeon interface Long Leg Alignment: (b)(4) Tibial Resection Level: (b)(4) Tibial Slope: (b)(4) Femoral Resection Level: (b)(4) Femoral Rotation: (b)(4)	Selected by the surgeon via the Smith and Nephew Patient Matched website Long Leg Alignment: Mechanical Axis Tibial Resection Level: Variable (range unspecified) Tibial Slope: Variable (range unspecified) Femoral Resection Level: Variable (range unspecified) Femoral Rotation: Epicondylar axis or Whitesides (AP Axis)
Indication For Use	The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting. The TruMatch™ Patient Specific Instruments are intended for use with existing DePuy Orthopaedics, Inc. knee systems and their cleared indications for use. The TruMatch™ Patient Specific Instruments are intended for single use only.	Smith & Nephew's Patient Matched Cutting Blocks are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting. The Patient Matched Cutting Blocks are intended for use with existing Smith & Nephew, Inc. knee systems and their cleared indications for use. The Patient Matched Cuffing Blocks are intended for single use only.

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Table 3: Comparison of TruMatch™ Patient Specific Instruments and HP (standard) Cutting Blocks

	TruMatch™ Cutting Blocks	**HP (standard)Cutting Blocks**
Implant Sizing	CT scan and (b)(4)	X-Ray and Templates
Femoral Resection Level	Surgeon Preference – Planned using long leg CT scan, Surgeon Input, and (b)(4); then built into cutting block. Illustrated below is the TruMatch™ (b)(4) (b)(4). Also illustrated is the TruMatch™ femoral cutting (b)(4). The TruMatch™ cutting slot is (b) mm thick and manufactured from (b) stainless steel. (b)(4)	Surgeon Preference - Planned using templates; resection level is set by adjusting features on cutting block. Illustrated below is the HP femoral locating device with (b)(4) (b) and the HP femoral cutting block (flag 2) attached to the femoral locating device and (b)(4). The HP cutting slot is (b)(4) mm thick and manufactured from (b) stainless steel. (b)(4)

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Tibial Resection Level	Surgeon Preference – Planned using long leg CT scan, Surgeon Input, and (b)(4); then built into cutting block. Illustrated below is the TruMatch™ (b)(4) Also illustrated is the TruMatch™ tibial cutting block (b)(4) The TruMatch™ cutting slot is (b) (b) thick and manufactured from (b) stainless steel.	Surgeon Preference - Planned using templates; resection level is set by adjusting features on cutting block. Illustrated below is the HP tibial cutting block and tibial stylus. The tibial stylus is pictured being adjusted to (b)(4)) and the HP tibial cutting block (flag 4) attached to the tibial stylus and positioned to (b)(4). The HP cutting slot is (b)(4) thick and manufactured from (b) stainless steel. 

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Femoral Rotation	Surgeon Preference – Planned using CT scan, surgeon input, and (b)(4); then built into cutting block. Illustrated below is the TruMatch™ (b)(4) Also illustrated is the TruMatch™ femoral cutting block with (b)(4) Flag 7 illustrates the femoral finishing block which is placed using the two previously drilled holes and used to guide a saw to finish the femoral bone cuts. (b)(4)	Surgeon Preference - Rotation is set by selecting an instrument to be used with cutting block. Illustrated below is the Sigma HP femoral sizing and rotation guide. DePuy offers four variants of rotation guides. They allow for (b)(4) referenced from the (b)(4)

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Tibial Slope	Surgeon Preference – Planned using CT scan and (b)(4) (b)(4) ; then built into cutting block	Surgeon Preference - Planned using templates; slope is set by adjusting features on cutting block
Leg Alignment	Mechanical axis and Surgeon Preference – Planned using long leg CT scan and (b)(4) ; then built into cutting block	Mechanical axis and Surgeon Preference - Planned using templates; alignment is set by adjusting features on cutting block.
Alignment Verification	Verified with HP alignment rod.	Verified with HP alignment rod
Alignment Options	Selected by the surgeon via the TruMatch™ (b) (4) (b)(4) . Long Leg Alignment: (b)(4) Tibial Resection Level: (b)(4) Tibial Slope: (b)(4) Femoral Resection Level: (b)(4) Femoral Rotation: (b)(4)	Selected by the surgeon by adjusting cutting blocks in the Operating room. Long Leg Alignment: (b)(4) Tibial Resection Level: (b)(4) Tibial Slope: (b)(4) Femoral Resection Level: (b)(4) Femoral Rotation: (b)(4)
Indication For Use	The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting. The TruMatch™ Patient Specific Instruments are intended for use with existing DePuy Orthopaedics, Inc. knee systems and their cleared indications for use. The TruMatch™ Patient Specific Instruments are intended for single use only.	The HP cutting blocks are indicated for use in orthopedic surgery to assist in shaping a patient's bone tissue to receive an implant during joint replacement surgery.

The clearance letter for the Smith & Nephew Patient Matched Cutting Blocks is provided in Exhibit B.

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11. PROPOSED LABELING

Draft labels, surgical techniques and a draft package insert for the proposed devices are provided in Exhibit C. Please note that patient name, date of birth, surgeon name, system, and use with information is populated on the label for each individual patient based on information the surgeon provides via the (b)(4).

12. STERILIZATION AND SHELF LIFE

The packaging materials protecting sterility of the TruMatch™ Patient Specific Instruments are (b)(4).

Sterilization is by (b)(4) where the TruMatch™ Patient Specific Instruments require a dose of (b)(4) sterilization is validated according to ISO (b)(4).

Packaging for the TruMatch™ Patient Specific Instruments has been validated for a shelf life of 11 years.

Sterility Assurance Level (SAL)

The SAL for all components is 10(

Pyrogenicity

No claims regarding pyrogenicity will be made. No pyrogen testing is conducted.

13. BIOCOMPATIBILITY

TruMatch™ Patient Specific Instruments are manufactured from two materials – (b)(4) Stainless steel and Renshape (b))(4)

Biocompatibility of the cured Renshape (b)(4) material was demonstrated by completion of the (b)(4) recommended tests for compliance to the standard: (b)(4) Refer to Exhibit D for copies of these test reports.

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(b)(4) [redacted] Per the requirements, three tests were performed and the acceptance criteria have been met.

14. SOFTWARE

N/A - There is no software contained in these medical devices.

15. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

N/A - These device designs contain no electronic components.

16. PERFORMANCE TESTING – BENCH

DePuy Orthopaedics, Inc. is not aware of any performance standards developed for these devices under Section 514 of the Federal Food, Drug and Cosmetic Act.

The following tests were conducted on the TruMatch™ Patient Specific Cutting Blocks:

- TruMatch™ Dimensional Stability Test
- Cadaver Accuracy Study
- Design Process and Design Software Repeatability Study
- Software Validation and Verification Summary

The tests are summarized below and demonstrate that all acceptance criteria were met; complete copies of the Dimensional Stability Test, Cadaver Accuracy Study and the Design Process and Design Software Repeatability Study are included in Exhibit E.

TruMatch™ Dimensional Stability Test

(b)(4) Testing [redacted]

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4) Testing

[redacted]

Cadaver Accuracy Study (b)(4)

(b)(4)

[redacted]

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(b)(4) Testing

[redacted]

Test Report Summary - TruMatch Design Process and Design Software Repeatability Study

(b)(4) Testing

[redacted]

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(b)(4) Testing

[redacted]

Test Report Summary – Software Verification and Validation Summary

(b)(4) Testing

[redacted]

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(b)(4) Testing



17. PERFORMANCE TESTING – ANIMAL

Animal testing was not performed, because substantial equivalence of these devices to the predicate devices could be demonstrated through bench testing.

18. PERFORMANCE TESTING – CLINICAL

Clinical testing was not performed, because substantial equivalence of these devices to the predicate devices could be demonstrated through bench testing.

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EXHIBIT A:

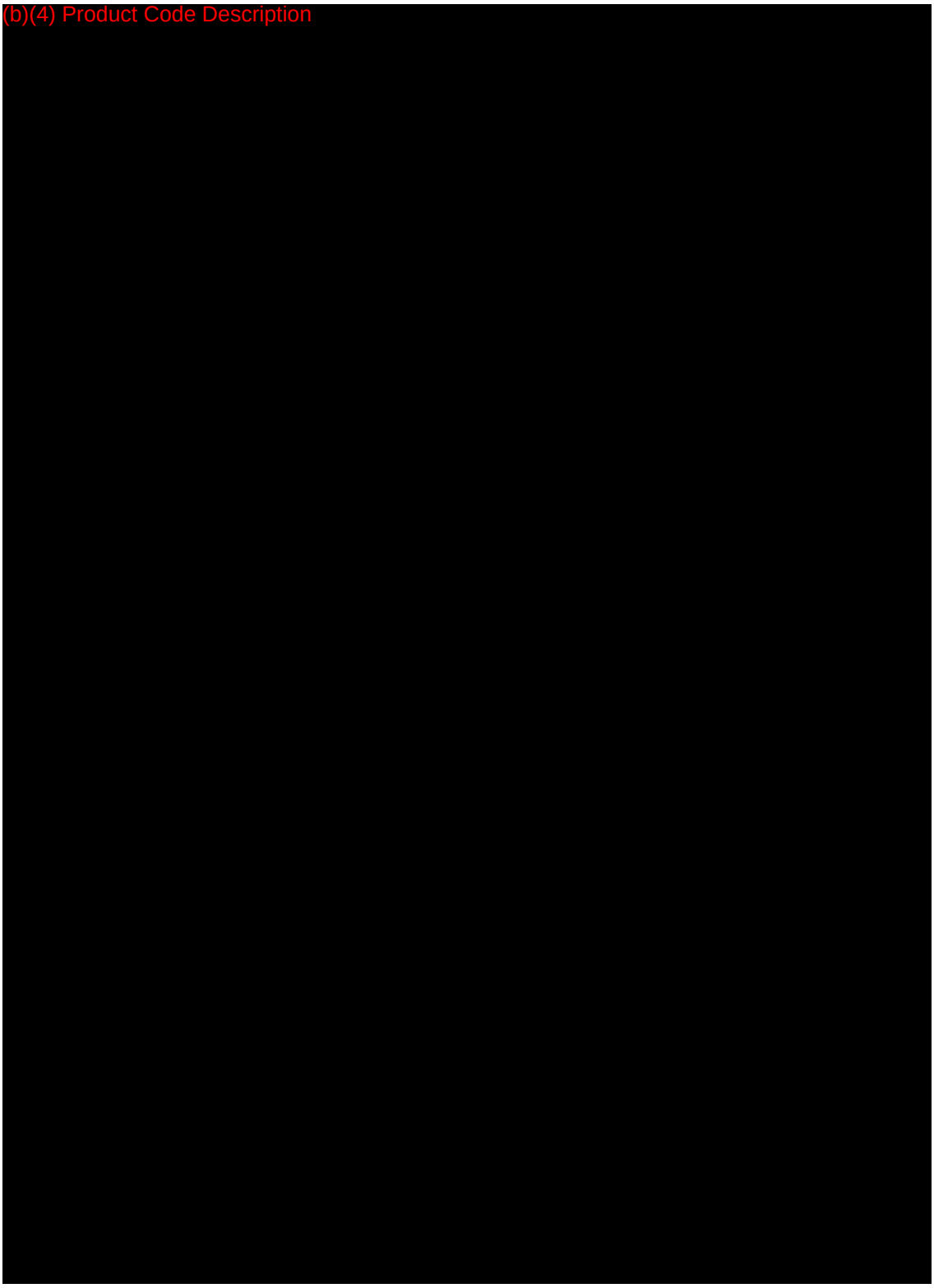
PART NUMBERS, DESCRIPTIONS AND ENGINEERING DRAWINGS

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Product Code	Description
(b)(4)	[redacted]

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(b)(4) Product Code Description



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

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

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EXHIBIT B:

PREDICATE DEVICE CLEARANCE LETTER

AND SURGICAL TECHNIQUE

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

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NOV 25 2008

510(k) Summary
Smith & Nephew, Inc. Patient Matched Cutting Blocks

Submitter's Name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's Address:	1450 Brooks Road, Memphis, TN 38116
Submitter's Telephone Number:	901-399-5340
Contact Person:	Megan Bevill
Date Summary Prepared:	November 17, 2008
Trade or Proprietary Device Name:	Patient Matched Cutting Blocks
Common or Usual Name:	Knee Prosthesis
Classification Name:	21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics 87/JWH, MBH

Device Description

Subject of this premarket notification are Smith & Nephew's Patient Matched Cutting Blocks. The Patient Matched Cutting Blocks are designed and manufactured from patient imaging data (MRI, CT, X-Ray).

Intended Use and Indications

Smith & Nephew's Patient Matched Cutting Blocks are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting.

The Patient Matched Cutting Blocks are intended for use with existing Smith & Nephew, Inc. knee systems and their cleared indications for use.

The Patient Matched Cutting Blocks are intended for single use only.

Substantial Equivalence

The design and intended use of the Patient Matched Cutting Blocks are substantially equivalent to Smith & Nephew, Inc.'s distal femoral and proximal tibial cutting blocks which are used in conjunction with the Smith & Nephew, Inc. implant systems identified in the table below.

System	510(k)	Clearance Date
Genesis II Knee System	K951987 K962137 K962557 K030612 K032683	8/22/1995 8/2/1996 12/5/1996 5/27/2003 8/28/2003
Legion Knee System	K073325	12/20/2007
Journey BCS Knee System	K042515	3/14/2005

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
Orthopaedic Division
% Ms. Megan Bevill
Regulatory Affairs Specialist
1450 East Brooks Road
Memphis, Tennessee 38116

NOV 2 5 2008

Re: K082358
Trade/Device Name: Patient Matched Cutting Blocks
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: JWH, MBH
Dated: November 14, 2008
Received: November 18, 2008

Dear Ms. Bevill:

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

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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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
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-POSTSTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number (if known): K082358

Device Name: Smith & Nephew, Inc. Patient Matched Cutting Blocks

Indications for Use:

Smith & Nephew's Patient Matched Cutting Blocks are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting.

The Patient Matched Cutting Blocks are intended for use with existing Smith & Nephew, Inc. knee systems and their cleared indications for use.

The Patient Matched Cutting Blocks are intended for single use only.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K082358

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

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VISIONAIRE®
Patient Matched Instrumentation

A technology from smith&nephew

Patient Matched Cutting Blocks Surgical Procedure: GENESIS® II, LEGION® PRIMARY or JOURNEY® BCS knee systems

Tip: Do not remove osteophytes before testing block fit; if there is an osteophyte that is causing the block not to sit properly on the bone, only remove the specific osteophyte impinging the fit then attempt to seat the block again

Femoral Block:

Exposure

Be sure to remove all soft tissue from the anterior cortex using a flat Hohmann retractor

Pinning and Drilling

1. Place femoral cutting block on the distal femur by pushing the block into the trochlear groove and down on the distal condyles

Tip: The proximal part of the femoral block should rest on the anterior cortex to ensure that the block is not in flexion

2. Allow the surgical assistant to firmly hold the block in place while the surgeon drills through the two distal holes using the 1/8 inch drill bit

3. Insert either long headed pins (45mm) or 45mm bone spikes into the distal holes that were drilled in step 3

4. With the distal pins in place, pin the anterior face of the block using either 45mm speed pins or by drilling through the holes and using long (45mm) bone spikes to secure the anterior face of the block

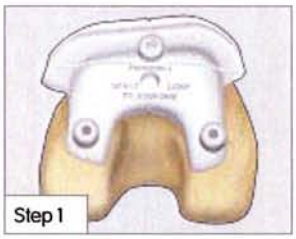
5. Use the slot alignment checker to determine if proper alignment will be achieved with the distal cut

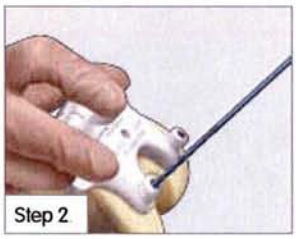
Note: The vertical etching represents the AP axis which can be used with the perpendicular epis to show rotational alignment

6. Remove the distal pins and make the distal cut

7. Proceed with the remaining femoral cuts by using the appropriately sized AP cutting block

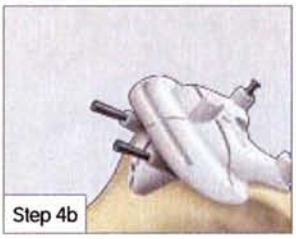
Note: The distal pinholes of the patient matched femoral cutting block match the pinholes for the 4-in-1 AP cutting block

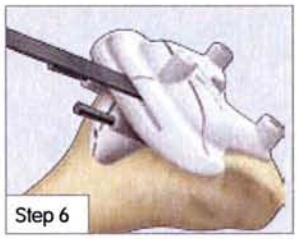

Step 1

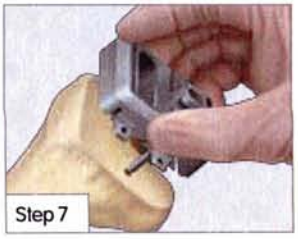

Step 2


Step 3


Step 4a


Step 4b


Step 6


Step 7

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

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Tibia Block:

Positioning and Exposure

Sublux the tibia

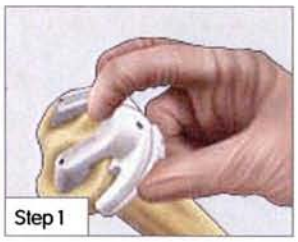
2. Remove the meniscus

3. Make sure all the proximal anterior loose soft tissue fibers have been removed

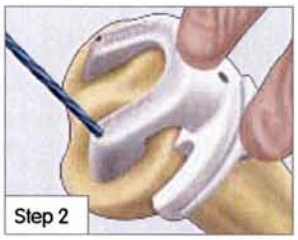
Pinning and Drilling

1. Place the tibial block on the proximal tibia. The key contact points for the tibial block are the medial and lateral plateaus and the anterior medial tibial face

Note: The cutting block should be resting flush on all three surfaces; if the block is not resting flush, remove any osteophytes or soft tissue that is impinging the fit

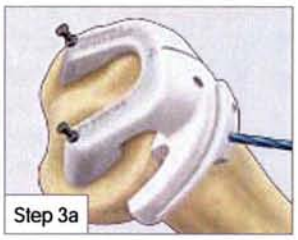


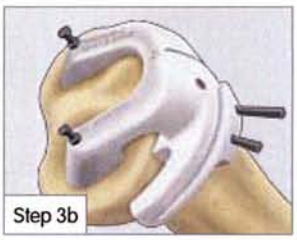
2. With the surgical assistant firmly holding the block in place, drill and pin the two proximal holes using either long (45mm) bone spikes or 45mm headed pins



3. With the proximal pins in place, pin the anterior face of the block using either 45mm speed pins or by drilling through the two holes and using long (45mm) bone spikes to secure anterior face of the block in place

Tip: This is important to ensure that the tibia does not rotate or change varus/valgus while pinning anteriorly





The additional anterior hole above the slot can be used to further secure the block during resection

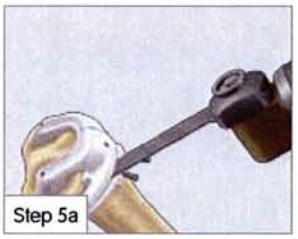
4. Use the slot alignment checker and drop rod check to ensure proper alignment will be achieved with the proximal tibial cut

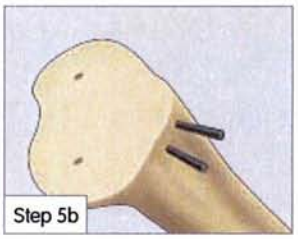
Note: The anterior etch marks the medial third of the tibia tubercle for tibia rotation; this can also can be used to line up the drop rod for checking v/v and slope

5. Remove the proximal pins and resect the tibia

6. Proceed to tibia trialing

Note: The pinholes on the tibial trial match the proximal pinholes of the patient matched tibial cutting block





Orthopaedic Reconstruction & Trauma – Smith & Nephew, Inc., 1450 Brooks Road, Memphis, TN 38116, USA
Phone: 1-901-396-2121, Information: 1-800-821-5700, Orders/inquiries: 1-800-238-7538
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7128-1512 40980101 03/09

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EXHIBIT C:

DRAFT PACKAGE LABELS, DRAFT PACKAGE INSERT AND SURGICAL TECHNIQUES

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Agile Label Number: LCN-420891 Shelf Life Days: 120 Label Stock Number: 0900-00-128
0900-00-129

OUTER

REF 420891 LOT SAMPLE STERILE R YYYY-MM

TruMatch™ PERSONALIZED SOLUTIONS

RESECTION GUIDE SET FOR SIGMA®



3	TIBIAL	RIGHT
2	FEMORAL	

+H44142089116

DePuy a Johnson-Johnson company

+$$3100914SAMPLE65

QTY 2

TruMatch™ PERSONALIZED SOLUTIONS

PATIENT NAME: NOM DU MALADE; PATIENTENNAME; NAAM VAN DE PATIËNT; NOME DEL PAZIENTE; NOMBRE DEL PACIENTE; NOME DO DOENTE

PATIENT DATE OF BIRTH: (Month/Day/Year) DATE DE NAISSANCE PATIENT (MOIS/JOUR/ANNÉE); PATIENTEN-GEBURTSDATUM (MONAT/TAG/JAHR); GEBOORTEDATUM PATIËNT (DAG/MAAND/JAAR); DATA DI NASCITA PAZIENTE (MESE/GIORNO/ANNO); FECHA DE NACIMIENTO PACIENTE (MES/DÍA/AÑO); DATA DE NASCIVENTO DO PACIENTE (MÊS/DIA/ANO)

SURGEON NAME: Nom du chirurgien; Name des Chirurgen; Naam chirurg; Nome del chirurgo ; Nombre del Cirujano; Nome do Cirurgião

SYSTEM: SYSTEME; SYSTEM; SYSTEEM; SISTEMA; SISTEMA; SISTEMA

JEU GUIDE RÉSECTION POUR SIGMA®; TAILLE 3 TIBIAL; TAILLE 2 FÉMORAL; DROITE
RESEKTIONSFÜHRUNGSSATZ FÜR SIGMA®; GRÖSSE 3 TIBIAL; GRÖSSE 2 FEMORAL; RECHTS
RESECTIEGELEIDER VOOR SIGMA®; MAAT 3 TIBIAAL; MAAT 2 FEMORAAL; RECHTS
SET GUIDA DI RESEZIONE PER SIGMA®; MISURA 3 TIBIALE; MISURA 2 FEMORALE; DESTRA
JUEGO GUÍA DE RESECCIÓN PARA SIGMA®; TAMAÑO 3 TIBIAL; TAMAÑO 2 FEMORAL; DERECHA
GUIA DE RESECÇÃO PARA SIGMA®; TAMANHO 3 TIBIAL; TAMANHO 2 FEMORAL; DIREITA

℞ Only ⚠ 2

MATL RenShape/SS

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Warsaw IN 46582
1-800-366-8143

EC REP DePuy International Ltd
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Leeds LS11 8DT England
+44(113)270-0461

REF 420891 LOT SAMPLE

REV D

PATIENT/INNER

0900-00-128 JTE526.lwl

REF 420891
LOT SAMPLE

DE'EX OCT

REF 420891 LOT SAMPLE STERILE R YYYY-MM
TruMatch™ * RESECTION GUIDE SET FOR SIGMA® * * * *
TIBIAL SIZE 3 * FEMORAL SIZE 2 * RIGHT

QTY 2

+H44142089116

+$$3100914SAMPLE65

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REF 420900 LOT SAMPLE STERILE R YYYY-MM

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PIN GUIDE SET

FOR USE WITH: **RIGHT**

+H4414206791A

+$$3110126SAMPLEA5

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QTY 2

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PATIENT NAME/DATE OF BIRTH: (Month/Day/Year)

NOM DU MALADE; PATIENTENNAME; NAAM VAN DE PATIËNT; NOME DEL PAZIENTE; NOMBRE DEL PACIENTE; NOME DO DOENTE
DATE DE NAISSANCE PATIENT (MOIS/JOUR/ANNÉE); PATIENTEN-GEBURTSDATUM (MONAT/TAG/JAHR); GEBOORTEDATUM PATIËNT (DAG/MAAND/JAAR); DATA DI NASCITA PAZIENTE (MESE/GIORNO/ANNO); FECHA DE NACIMIENTO PACIENTE (MES/DÍA/AÑO); DATA DE NASCIMENTO DO PACIENTE (MÊS/DIA/ANO)

SURGEON NAME:

Nom du chirurgien; Name des Chirurgen; Naam chirurg; Nome del chirurgo ; Nombre del Cirujano; Nome do Cirurgião

SYSTEM:

SYSTEME; SYSTEM; SYSTEEM; SISTEMA; SISTEMA; SISTEMA

PIN GUIDE SET; DROITE;
PIN GUIDE SET; RECHTS;
PIN GUIDE SET; RECHTS;
PIN GUIDE SET; DESTRA;
PIN GUIDE SET; DERECHA;
PIN GUIDE SET; DIREITA;

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REF 420900 LOT SAMPLE REV A

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REF	Catalog Number
LOT	Batch Code
STERILE R	Sterilized Using Irradiation
	Use By
	Do Not Reuse
	Attention: See Instructions for Use
	Manufacturer
	Do Not Use if Package is Damaged

0901-04-148 REV. A

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IMPORTANT INFORMATION - Please Read Before Use

INFORMATIONS IMPORTANTES - À lire attentivement avant d'utiliser

WICHTIGE INFORMATIONEN - Vor Gebrauch bitte lesen

INFORMACIÓN IMPORTANTE - Sírvase leerla antes de emplear

INFORMAZIONI IMPORTANTI - Leggere prima dell'uso

INFORMAÇÃO IMPORTANTE - É favor ler antes de utilizar

BELANGRIJKE INFORMATIE - Vóór gebruik lezen

VIGTIG INFORMATION - Læses før brug

VIKTIGT! - Läs detta innan produkten används

TÄRKEÄÄ - Lue ennen käyttöä

ΣΗΜΑΝΤΙΚΕΣ ΠΛΗΡΟΦΟΡΙΕΣ - Παρακαλούμε διαβάστε πριν από τη χρήση

DŮLEŽITÉ INFORMACE - Před použitím si prosím přečtěte tento leták

FONTOS INFORMÁCIÓ - Használat előtt elolvasandó

WAŻNE INFORMACJE - Prosimy przeczytać przed użyciem

DÔLEŽITÉ INFORMÁCIE - Prečítajte si láskavo ešte pred použitím

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IFU-0902-00-831
Rev. D

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STERILE, SURGICAL INSTRUMENTS (TruMatch™)

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ENGLISH **INSTRUCTIONS FOR USE**

2 **STERILE** See product label for method

Most instrument systems include trays and a container(s). Patient Specific instruments are intended for use with a specific implant. It is essential that the surgeon and operating theatre staff are fully conversant with the appropriate surgical technique for the implants and associated instruments.

TruMatch™ Devices are Patient Specific Custom Made Devices. Patient Specific Instruments are provided STERILE. Single Use devices are designed to be used only once, for a single patient. Instruments provided STERILE are available for immediate use in the operating theatre using appropriate aseptic techniques.

DO NOT RESTERILIZE and DO NOT USE if the package is damaged or broken and sterility may be compromised.

The TruMatch Personalized Solutions system is currently targeted for patients with osteoarthritis who:

Meet the criteria for primary fixed and mobile bearing total knee replacement performed with a measured resection technique.

Have mild bone deformities and/or angular deformities less than 15 degrees of fixed varus/valgus, or flexion.

Some previous implants are acceptable, including hip implants, ankle implants, and soft tissue anchors. Contralateral knee replacement is acceptable as long as the contralateral knee is flexed away (not within the same medial/lateral axis) from the knee of interest during the CT scan.

Indications for Use:

The TruMatch Personalized Solutions system is intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The TruMatch Personalized Solutions system is intended for use with existing DePuy Orthopaedics, Inc. knee systems and their cleared indications for use.

The TruMatch Personalized Solutions system is intended for single use only.

Contraindications:

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The following conditions are not compatible with the TruMatch Personalized Solutions:

- Previous knee replacement of the same knee.

Cautions:

- Any metal device that will cause scatter in the CT through the knee.
- Angular deformities greater than 15 degrees of fixed varus, valgus, flexion, or tibial slope exceeding 15 degrees.
- Moderate to severe bony deformities, charcot knee, or patients with severe patella tendon calcification that may prevent patella eversion.

For instruments produced by another manufacturer, reference the manufacturer's instructions for use.

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

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INTERPRETATION OF SYMBOLS

SIGNIFICATION DES SYMBOLES

BEDEUTUNG DER SYMBOLE

INTERPRETACIÓN DE SÍMBOLOS

INTERPRETAZIONE DEI SIMBOLI

INTERPRETAÇÃO DE SÍMBOLOS

BETEKENIS VAN DE SYMBOLEN

BETYDNING AF SYMBOLER

FÖRKLARNING AV OLIKA SYMBOLERS BETYDELSE

SYMBOLIEN SELITYKSET

EPMHNEIA ΣΥΜΒΟΛΩΝ

VYSVĚTLIVKY VÝRAZŮ A SYMBOLŮ

MAGYARÁZAT A HASZNÁLT JELEKHEZ ÉS KIFEJÉZÉSEKHEZ

ZNACZENIE SYMBOLI I TERMINÓW

VYSVETLENIE TERMÍNOV A SYMBOLOV

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Symbol to be Included in IFU	Interpretation	Symbol(s)
✓	DEPUY, INC.	D/DP
✓	QUANTITY	QTY
✓	MATERIAL	MATL
✓	MANUFACTURED BY:	MFG and MFG/MANUFACTURED BY:
✓	SIZE	SIZE and SZ
✓	CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN	Rx Only
✓	DO NOT RESTERILIZE	
✓	DO NOT USE IF PACKAGE IS DAMAGED	
✓	For recognized manufacturer, refer to product label.	For recognized manufacturer, refer to product label.
✓	RenShape/Stainless Steel	RenShape/SS

* **DePuy (Ireland)**
Loughbeg, Ringaskiddy
Co. Cork
Ireland

* **DePuy Orthopaedics, Inc**
700 Orthopaedic Drive
Warsaw, IN 46582
USA

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Tel: +353 214914278
Fax: +353 214914199

Tel: 1 +(800) 366 8143

DePuy International Ltd.
* St. Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 270 0461
Fax: +44 (113) 272 4101

*** For recognized manufacturer, refer to product label.**

US REP

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46582
USA
Tel: 1 +(800) 366 8143

EC REP

DePuy International Ltd.
St. Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 270 0461
Fax: +44 (113) 272 4101

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IFU-0902-00-831
Rev. D

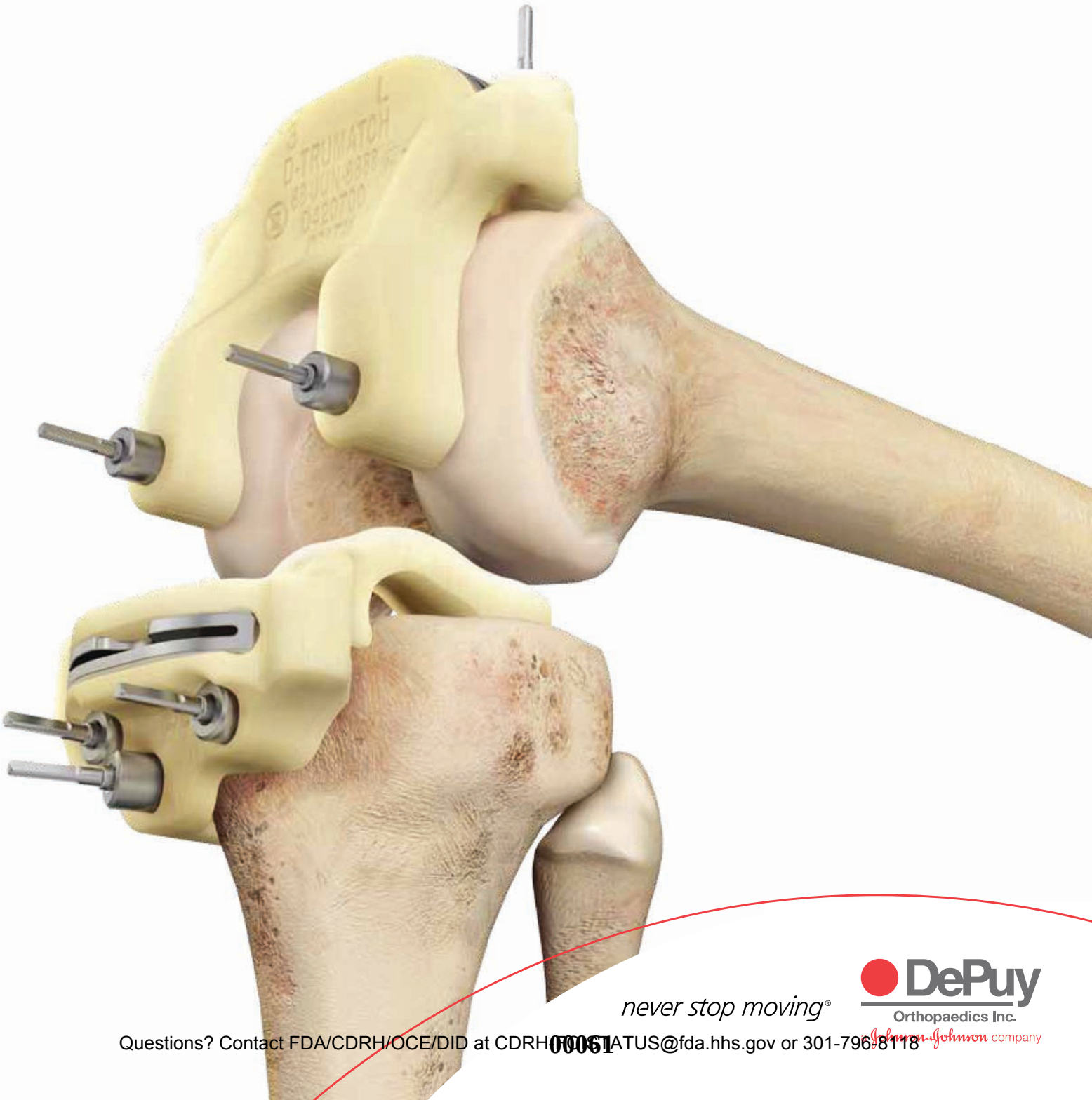
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TruMatch™ PERSONALIZED SOLUTIONS | SIGMA® HIGH PERFORMANCE INSTRUMENTS

TruMatch™ Personalized Solutions Surgical Technique

with the Sigma® High Performance Instruments System



never stop moving®

DePuy Orthopaedics Inc. Johnson & Johnson company

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The following steps are an addendum to the Sigma® High Performance (HP) Instruments, Fixed Reference Surgical Technique (Cat. No. 0612-87-510).

This surgical technique provides instruction on how to incorporate the TruMatch™ femoral alignment/distal and tibial alignment/proximal resection guides into the broader Sigma HP Instruments Fixed Reference Surgical Technique. As such, the surgeon must be familiar with the proper use of the Sigma HP Instruments, as these are required in steps prior to, and following, the utilization of the TruMatch femoral and tibial resection guides.



TruMatch™
PERSONALIZED SOLUTIONS

Ref. Case #: CPR0039M
OrderType: TKA
Confidential Information

Dr. TCBestUer2

Please review the following patient proposal. On your DePuy TruMatch website use the "Make Decision" button to select the appropriate status for this case. Once your approval and feedback has been submitted, manufacturing of the custom guides will begin.

Please contact DePuy TruMatch Support if you have any questions or need further information.
Toll Free number: 1-800-689-0746
Email: TruMatchSupport@depuyusjnj.com

Cordially,
DePuy Orthopaedics
DePuy Orthopaedics - TruMatch Design Team

Patient Name: [redacted]
Gender: M DOB: 1945-01-12 Height: 5 ft, 10 in Weight: 220 lb Affected Side: L
Patient Special Considerations:
Profile: Varus Cartilage Loss: M: 100% L: 75% Surgery Date: 2011-01-07

Surgeon Name: [redacted] Facility: St. Mary 's
Contact Email: [redacted]
Device Information:
Implant System: PFC Sigma Instrument System: HP
Fem. Component: Sz 6 PSL Poly Component: Sz 6 Tib Component: Fixed Bearing

Alignment: (NOTE: All TruMatch resections are planned with varus/valgus angle perpendicular to the mechanical axis)
Fem. Sizing Ref.: Anterior Down External Rotation Ref.: Posterior Condyles External Rot.: 0°
Distal Fem. Resect: 5.0 + 1.0 = 6.0 Distal Resection Ref.: Mechanical Axis Valgus/Rot.: 0°
Prox. Tib. Resect: 5.0 + 0.0 = 5.0 Posterior Tib. Slope: 0°

Notes/Comments:

Proposal Revision: 2

Upon your approval, DePuy will manufacture the customized instruments based upon the listed information supplied by you. DePuy has not verified the information supplied by you and makes no warranty as to the correctness or applicability of such information in the customized instruments to be manufactured or supplied pursuant to your request and therefore makes no warranty and disclaims an implied warranty of merchantability or fitness for a particular purpose with respect to the customized instruments. DePuy does not warrant that the customized instruments to be supplied under this request are merchantable, of good quality and free from defects, whether patent or latent, in materials or workmanship, and that the customized instruments will hereunder conform to or exceed the applicable testing standards recognized by DePuy's industry. DePuy further warrants that it has good title to the customized instruments and that the customized instruments are free and clear from all chattel encumbrances.

Page 1 of 2

The surgeon must also carefully review the TruMatch Patient Proposal prior to proceeding with the surgical procedure. The Patient Proposal is available through the web-based, password protected, TruMatch Personalized Solutions portal.

The Patient Proposal contains in-depth information utilized in the design of the patient specific guides including, as necessary, requests that are listed in the Notes/Comments section, about resection of impinging osteophytes for proper block placement and fit.

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

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Basic TruMatch™ Surgical Steps

Femoral Preparation



Step 1: Femoral block positioning



Step 2: Placement of anterior pins



Step 3: Drill and placement of distal pins



Step 4: Distal femoral resection



Step 5: Use of the fixed reference guide to position the 4-in-1 chamfer block

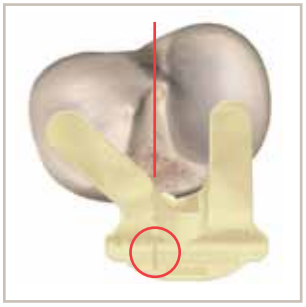


Step 6: Use of the angelwing to verify anterior resection.



Step 7: Placement of chamfer block pins and removal of the fixed reference guide

Tibial Preparation



Step 1: Tibial block placement aided by patient proposal



Step 2: Placement of two anterior pins



Step 3: V/V verification with alignment adapter and rod



Step 4: Placement of divergent, locking pin



Step 5: Tibial plateau resection

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

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Distal Femoral Resection

The femoral alignment/distal resection guide (as well as the packaging the guide comes in) will have patient specific identifiers: Patient Name, Patient D.O.B., Size and Patient Anatomy (R/L). Please verify the accuracy of these identifiers prior to use (Figure 1).



Figure 1

Place the femoral alignment/distal resection guide onto the distal aspect of the femur while in flexion of approximately 90 degrees (Figure 2). Due to the large amount of contact area between the guide and the bone, it may be easier to position the guide by seating the anterior aspect of the guide on the anterior cortex first (Figure 2 - lower left) and then toggle the device posteriorly. Avoid using excessive force to seat the guide, as it is not needed.

Note: *It may be necessary to clear extraneous tissue along the anterior cortex as this may cause the guide to not seat properly. Be careful to avoid any soft tissue impingement, as this will impact the overall alignment of the resection guide. Better visualization of the proper seating may be possible if the guide is viewed from a sagittal viewpoint. See the Surgical Tips and Pearls section for further information.*



Figure 2

Once the optimum position is found for the femoral alignment/distal resection guide, see that it allows no toggling or rocking. It is not uncommon to see a 2 to 3 mm gap around the periphery of the guide due to cartilage loss.

When placement is optimized, secure the femoral alignment/distal resection guide by inserting one threaded 3.25 mm pin through the anterior medial hole (Figure 3). After the medial pin is secured, place another pin through the lateral pin hole (Figure 3).



Figure 3

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

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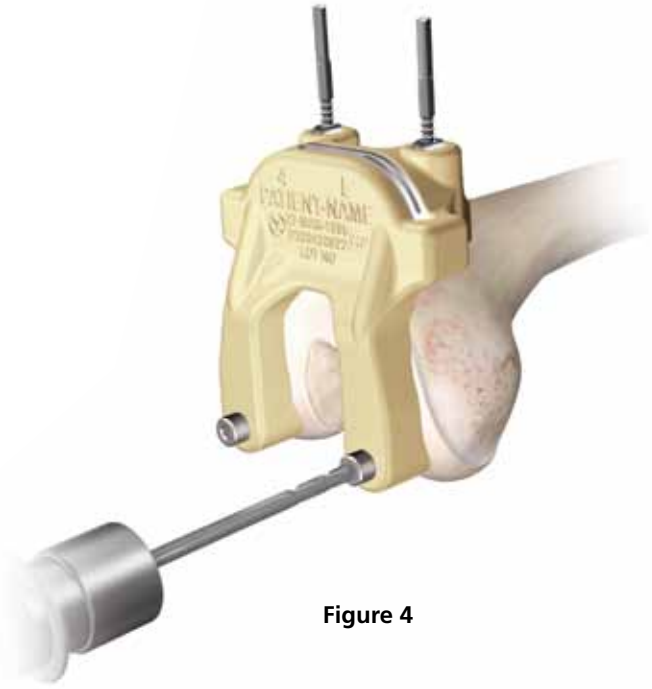


Figure 4

After the femoral alignment/distal resection guide is secured, drill the two distal holes with a 3.25 mm drill bit. These pin holes set the femoral rotation and match the A/P chamfer block from the standard instrument set (Figure 4).

Prior to cutting, the pin may be removed. However, it is recommended to perform the distal femoral resection by leaving one distal pin in the block while resecting the opposite side of the femur.



Figure 5

Perform the distal femoral resection with a 1.19 mm blade (Figure 5).

Remove femoral alignment/distal resection guide. Make sure bone cuts are clean and void of any under-cut bone fragments.

Note: *In order to adjust ligament tension, it may be necessary to re-cut the distal aspect of the femur or the proximal aspect of the tibia to achieve proper balance. In these instances, the anterior location of the pins are compatible with the regular HP Instruments distal femoral cutting or tibial resection guides. Both guides can be used to cut either 2 or 4 mm of additional bone. These guides fit over pins placed in the previously drilled guide pin locations.*

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

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Femoral Preparation - A/P and Chamfer Cuts

Attach the Universal Handle to the Fixed Reference Guide (Cat. No. 2004-20-920) and position the guide's spikes on the 0 mm pinholes of the Sigma Fixed Reference A/P chamfer block (Figure 6). Once the handle/guide/ block assembly is put together, insert the guide's spikes into the existing holes located on the distal femoral bone cut.

Note: *The TruMatch femoral block is designed to position the pin holes posteriorly while maintaining the desired "anterior down" or "posterior up" fixed reference selection. In addition, the Sigma RP-F and standard Sigma A/P and chamfer cutting blocks look very similar. Care should be taken not to confuse the blocks as this will result in under or over resection of the posterior condyles.*

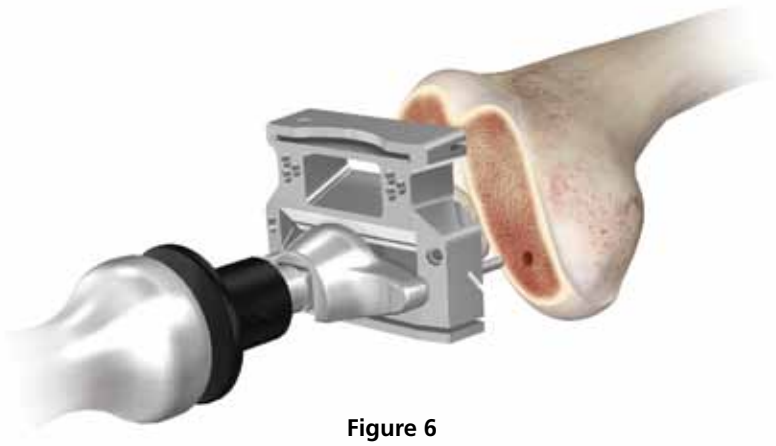


Figure 6

Confirm the anterior cut placement with the reference guide, or angelwing (Figure 7). If desired, the block may be shifted 2 mm anteriorly or posteriorly by selecting one of the offset holes around the "0" hole. When downsizing, using the smaller A/P chamfer block and the most anterior pin holes will take 2 mm more bone anteriorly and 2 mm less bone posteriorly.

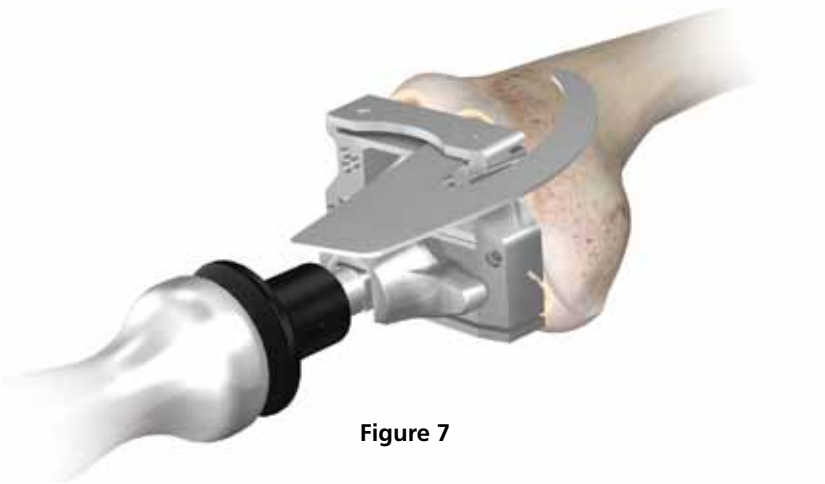


Figure 7

Secure the block's location by inserting threaded headed pins into the convergent pin holes on the medial and lateral aspect of the A/P chamfer block. Once completed, remove the handle/ fixed reference guide assembly and perform the femoral chamfer cuts in the regular manner (Figure 8).

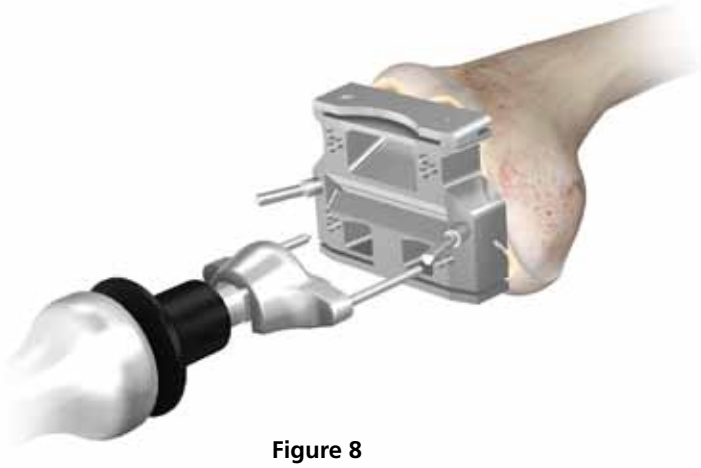


Figure 8

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Proximal Tibial Resection

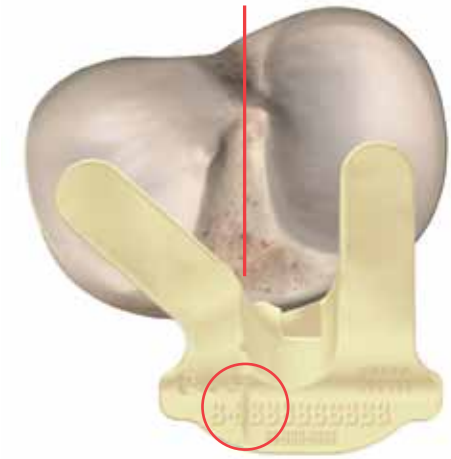


Figure 9

The tibial alignment/proximal resection guide (as well as the packaging the guide comes in) will have patient specific identifiers: Patient Name, Patient D.O.B., Size and Patient Anatomy (R/L). Please verify the accuracy of these identifiers prior to use (Figure 9).

Place the tibial alignment/distal resection guide onto the proximal aspect of the tibia while in flexion of approximately 90 degrees. Avoid using excessive force to seat the guide, as it is not needed. To assist in the M/L positioning of the tibial resection guide, the last page of the Patient Proposal document contains a top view of the tibial surface. As shown in the Proposal's patient specific view, align the line on top of the tibial resection guide with the one displayed on the tibial bone (Figure 10).

Note: *It may be necessary to clear extraneous tissue along the anterior aspect of the tibia as this may cause the guide to not seat properly. Be careful to avoid any soft tissue impingement, as this will impact the overall alignment of the resection guide. Better visualization of the proper seating may be possible if the guide is viewed from a sagittal viewpoint.*



To position the guide, it is helpful to apply approximately 25 percent pressure to the proximal aspect and 75 percent pressure to the anterior aspect of the guide. This will aid in seating the guide to arrive at the appropriate resection level. Once the optimum position is found for the tibial alignment/proximal resection guide, see that it allows little to no toggling or rocking.

When placement is optimized, secure the resection guide by inserting one non-headed threaded 3.25 mm pin through the medial hole. After the medial pin is secured, place another pin through the lateral pin hole (Figure 11).



Figure 11

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Proximal Tibial Resection (continued)

After selecting the proper R/L orientation of the Alignment Verification Adapter (Cat. No. 2000-42-062) (holes point laterally) insert one of the two HP Alignment Rods. Then, insert the adapter's blade into the resection guide's saw slot (Figure 12).



Figure 12

Confirm the Varus/ Valgus (V/V) position of the guide by verifying that the rod distally lies along, or parallel to, the patient's tibial crest. If the V/V alignment is not acceptable, check for proper seating, soft tissue impingement or proper M/L orientation of the resection guide. If necessary, remove the fixation pins and reposition the resection guide following the steps previously described. See Surgical Tips and Pearls section for further information.

Once the V/V alignment of the resection guide is satisfactory, insert an additional pin in the distal hole. This hole will place the pin in a divergent path to add stability (Figure 13).

Note: *Optionally, the tibial resection guide can be V/V aligned and fixed by a) positioning it M/L, as described, aided by the image in the Patient Proposal; b) inserting only the medial fixation pin; c) utilizing the alignment adapter/rod assembly, verify the V/V alignment of the guide d) manually holding the guide and inserting the remaining two fixation pins.*



Figure 13

Perform the proximal tibial resection with a 1.19 mm blade (Figure 14).

After removing all fixation pins and the tibial resection guide, make sure bone cuts are clean and void of any under-cut bone fragments.

Note: *If additional tibial resection or tibial slope is desired, replace the two proximal fixation pins and utilize the appropriate Sigma HP Instrument's tibial resection guide.*

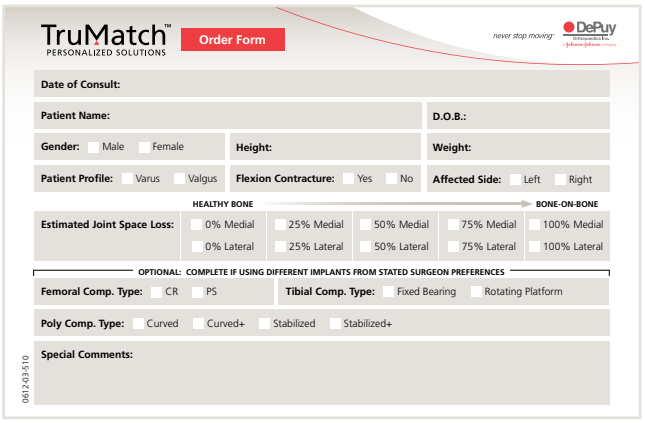
Proceed with the remaining steps for proximal tibial preparation as outlined by the Sigma HP Instruments Surgical Technique.



Figure 14

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

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TruMatch™ PERSONALIZED SOLUTIONS — Order Form — never stop moving — DePuy Orthopaedics, Inc. a Johnson & Johnson company

Date of Consult:

Patient Name: | D.O.B.:

Gender: ☐ Male ☐ Female | Height: | Weight:

Patient Profile: ☐ Varus ☐ Valgus | Flexion Contracture: ☐ Yes ☐ No | Affected Side: ☐ Left ☐ Right

HEALTHY BONE → BONE-ON-BONE

Estimated Joint Space Loss:	0% Medial / 0% Lateral	25% Medial / 25% Lateral	50% Medial / 50% Lateral	75% Medial / 75% Lateral	100% Medial / 100% Lateral

OPTIONAL: COMPLETE IF USING DIFFERENT IMPLANTS FROM STATED SURGEON PREFERENCES

Femoral Comp. Type: ☐ CR ☐ PS | Tibial Comp. Type: ☐ Fixed Bearing ☐ Rotating Platform

Poly Comp. Type: ☐ Curved ☐ Curved+ ☐ Stabilized ☐ Stabilized+

Special Comments:

0612-03-510

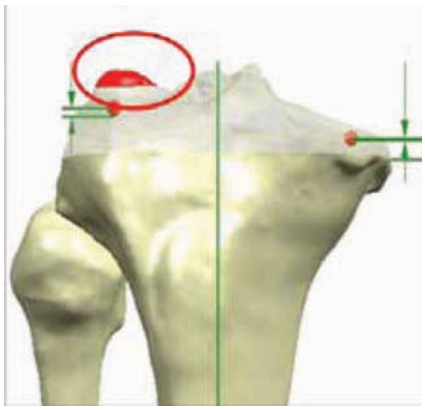


Figure 15

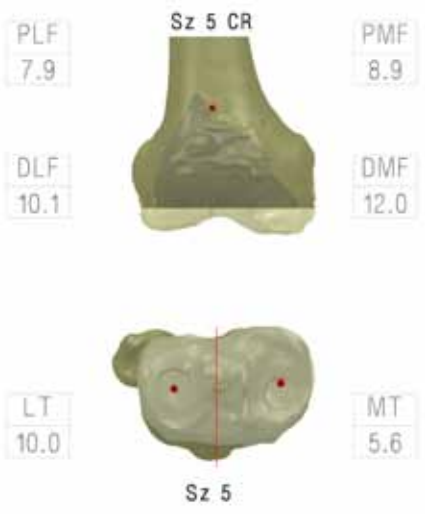


Figure 16

PREOPERATIVE

Order Form

a. Take careful consideration when estimating the M/L "Joint Space Loss" by utilizing weight bearing knee joint radiographs and providing it with the order submission. This value is an important part of the algorithm used to design the cartilage offset for proper positioning of the blocks.

Patient Proposal

a. Review in detail prior to the surgery.

b. Review the Notes/Comments section for information from the TruMatch design team regarding the design of the blocks and/or requests for removal of osteophytes.

c. Print in Color! Request for resection of osteophytes will be shown in red on the appropriate bone(s) (Figure 15).

d. For intraoperative reference, display at an easy to read area in the OR, such as the light box or back wall.

e. Review the intraoperative check-list (last page), which contains bone resection information and tibial block orientation view (Figure 16).

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

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INTRAOPERATIVE

Fixation Pins

a. The Sigma HP threaded, headless and sterile pins (9505-02-302), combined with the HP driver (9505-02-071), are recommended for firmly securing the blocks, especially for the tibial block when used on soft bone.

Femoral Resection Block

a. The femoral block's primary reference surface is the anterior cortex of the femur (Figure 17a). The upper most portion of the block should clear the anterior femoral flange and sit flush on the bone cortex. It may be necessary to remove the thin soft tissue to expose the underlying bone. When positioning the block, apply most of the pressure (~75%) against the anterior aspect of the femur.

b. Distally, a gap may be seen between the block and the femoral condyles (Figure 17b). If the block is securely positioned anteriorly, do not force the block's arms to sit flush on the femoral condyles. While applying anterior force apply light force (~25%) distal-to-proximal, to stabilize the block. Secure it by inserting the anterior fixation pins.

c. After performing the distal femoral resection and removing the block, examine the posterior aspect of the block's arms. If it appears to be damaged by the saw blade, that respective condyle cut was likely under cut and out of plan. The block should be repositioned and the cut repeated (Figure 18).

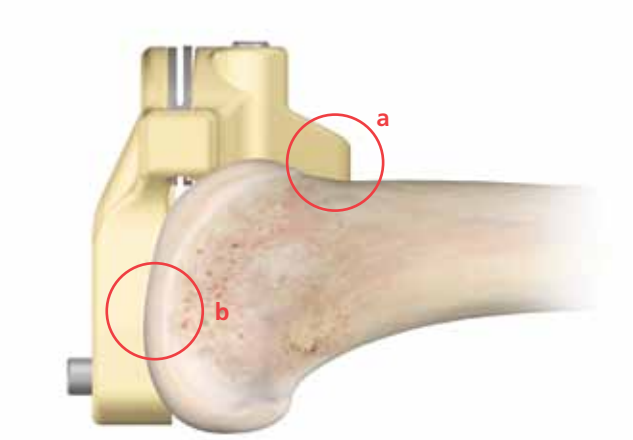


Figure 17

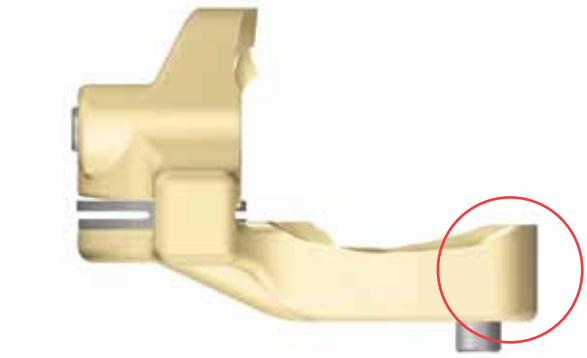


Figure 18

If the femoral block does not fit, verify the following:

1. Was the tissue in the anterior surface of the femur removed and is the proximal portion of the block sitting on bone?
2. Did the block upper portion clear the anterior femoral flange and is it sitting on the bone cortex?
3. Is the incision preventing placement of the block on the bone? The incision must provide a clear view of the block fit to bone.
4. Check the Patient Proposal, does it require removal of osteophytes? These are highlighted in red.

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

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Figure 19

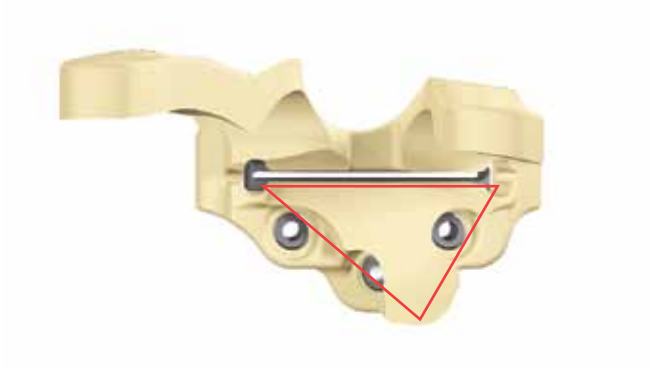


Figure 20

Tibial Resection Block

a. The tibial block's primary reference surface is the anterior/medial aspect of the tibia. This area, roughly triangular in shape, matches the block's largest surface contact area located below the saw slot (Figure 19). When positioning the block, apply most of the pressure (~75%) against the anterior aspect of the tibia. It may be necessary to remove the thin soft tissue, and/ or non-osseous ostephytes, to expose the underlying bone (Figure 20).

b. If the block is securely positioned anteriorly, do not force the block's arms to sit flush on the tibial plateau. While applying force anteriorly, apply light downward force (~25%) on the block's proximal arms to hold the block stable. Secure it by inserting the anterior fixation pins.

If the tibial block does not fit, verify the following:

1. Is the incision preventing placement of the block on the bone? The incision must provide a clear view of the block fit on the bone.
2. Check that the lateral aspect of the block is not sitting on the patellar tendon.
3. Confirm that both of the block's proximal arms are not impinged by tissue close to the tibial spine.
4. Check the Patient Proposal, does it require removal of osteophytes? These are highlighted in red.
5. Check the Patient Proposal, was the "Joint Space Loss" reported to be 100% for either of the condyles, although the actual patient has little to no joint space loss? If so, scrape the condyle where full joint loss was requested.

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The TruMatch Personalized Solutions system is currently targeted for patients with osteoarthritis who:

1) Meet the criteria for primary total knee replacement performed with a measured resection technique.

2) Have mild bone deformities and/or angular deformities less than 15 degrees of fixed varus, valgus, or flexion.

Some previous implants are acceptable, including hip implants, ankle implants, and soft tissue anchors. Contralateral knee replacement is acceptable as long as the contralateral knee is flexed away (not within the same medial/lateral axis) from the knee of interest during the CT scan. Please refer to the TruMatch CT Center User Guide for more information.

EXCLUSION CRITERIA:

The following conditions are not compatible with TruMatch Personalized Solutions:

- Previous knee replacement of the same knee.
- Femoral nails and bone plates that extend into the knee, or 8 cm from the joint line.
- Any metal device that will cause scatter in the CT through the knee.
- Angular deformities greater than 15 degrees of fixed varus, valgus, flexion, or tibial slope exceeding 15 degrees.
- Moderate to severe bony deformities, charcot knees, or patients with severe patella tendon calcification that may prevent patella eversion.

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
USA
Tel: +1 (800) 366 8143
Fax: +1 (574) 371 4865

DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 387 7800
Fax: +44 (113) 387 7890

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XX0410
0612-07-510 (Rev. 2)

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

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TruMatch™
PERSONALIZED SOLUTIONS

Pin Guide Surgical Technique

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TruMatch Pin Guide, Surgical Technique Summary

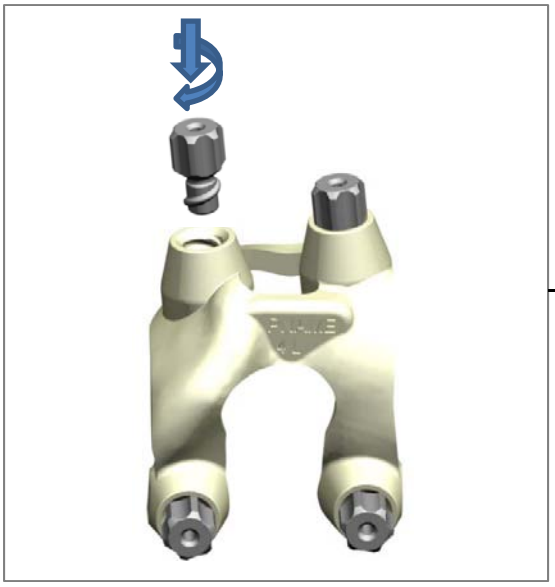
The following steps are an addendum to the Sigma® High Performance (HP) Instruments, Fixed Reference Surgical Technique (Cat. No. 0612-87-510). This surgical technique provides instruction on how to incorporate the TruMatch™ Pin Guide femoral alignment/distal and tibial alignment/proximal guides into the broader Sigma HP Instruments Fixed Reference Surgical Technique. As such, the surgeon must be familiar with the proper use of the Sigma HP Instruments, as these are required in steps prior to, and following, the utilization of the TruMatch femoral and tibial pin guides.

The surgeon must also carefully review the TruMatch Patient Proposal prior to proceeding with the surgical procedure.

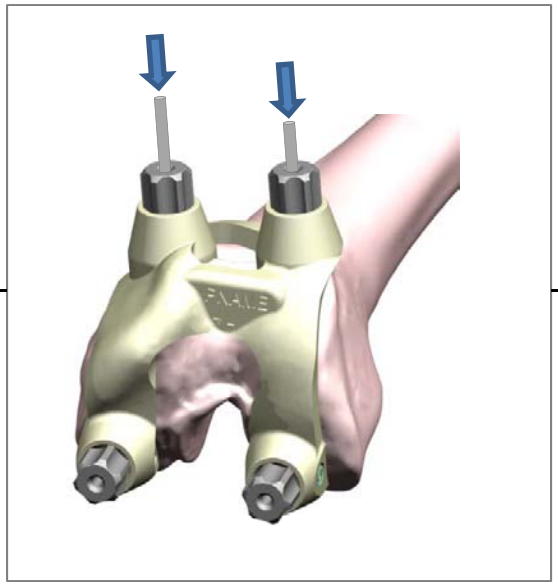
Questions? Contact FDA/CDRH/OCE/DID at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

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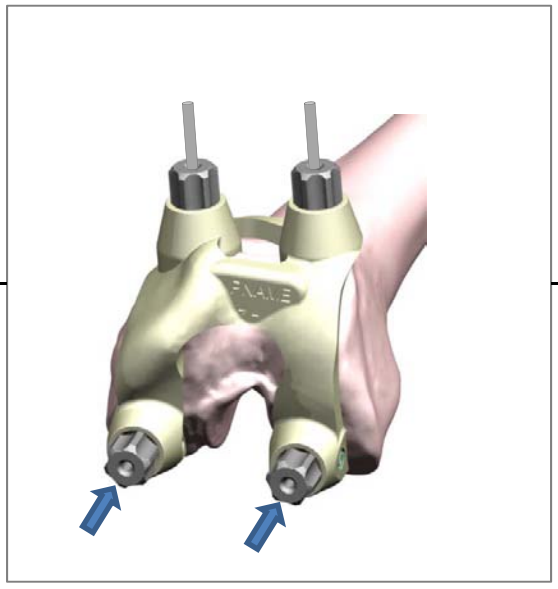
Basic TruMatch™ Surgical Steps - Femoral Preparation



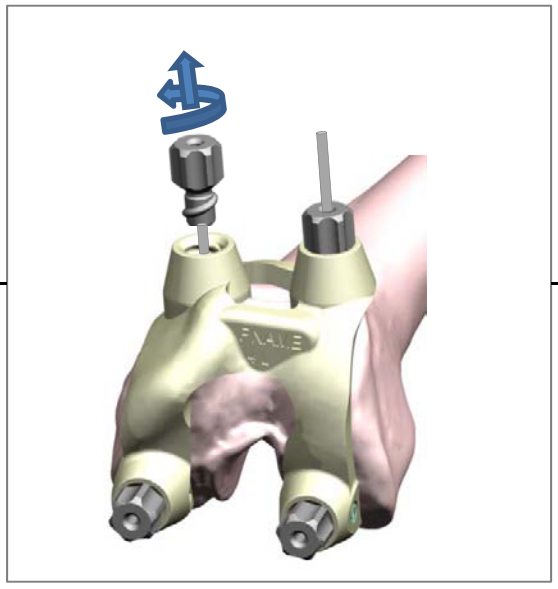
Step 1. With a clockwise twisting motion secure one metal Fast-Guide in each of four holes of the femoral pin guide.



Step 2. Place the femoral pin guide onto the distal femur and then insert 3.25 mm pins through each of the two anterior metal Fast-Guides.



Step 3. After the femoral pin guide is secured, drill the two distal holes with a 3.25 mm drill bit. These holes set the femoral rotation and match the fixed reference A/P chamfer block from the HP instrument set.



Step 4. With a counterclockwise twisting motion, remove the anterior Fast-Guides from the femoral pin guide. Remove the femoral pin guide by slightly flexing while, leaving in place, the two anterior pins.

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Basic TruMatch™ Surgical Steps - Femoral Preparation



Step 5. Select the appropriate distal femoral cutting guide. Perform the distal femoral resection.



Step 6. Use of the fixed reference guide to position the 4-in-1 chamfer block



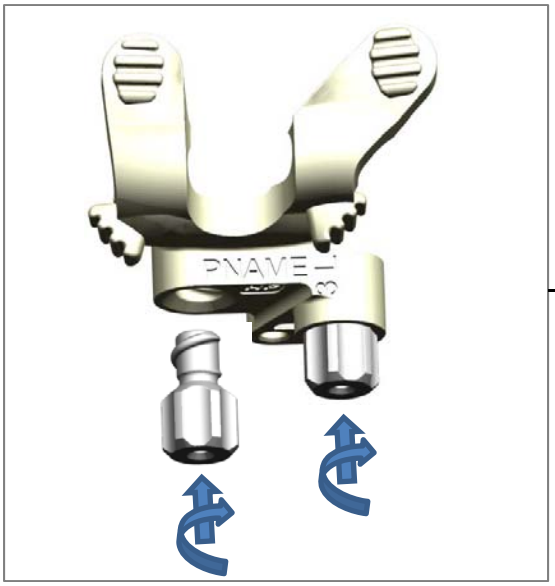
Step 7. Use the angel wing to verify anterior resection.



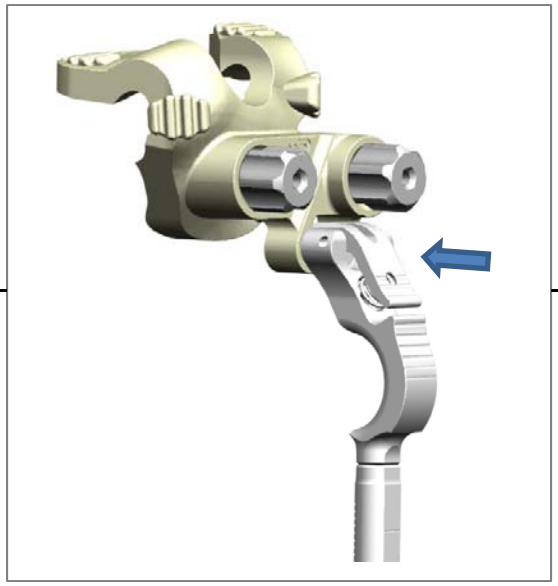
Step 8. Placement of the chamfer block pins and removal of the fixed reference guide.

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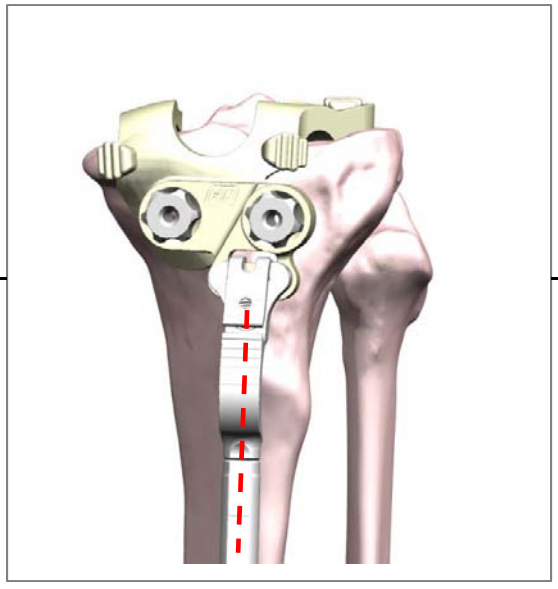
Basic TruMatch™ Surgical Steps – Tibial Preparation



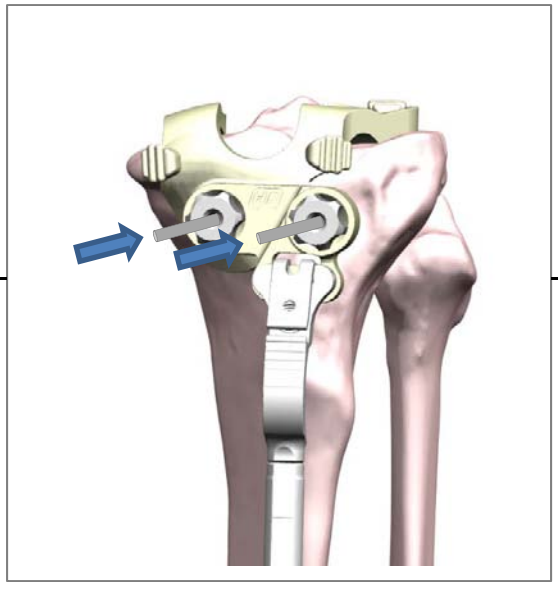
Step 1. With a clockwise twisting motion secure one metal Fast-Guide in each of two holes in the tibial pin guide.



Step 2. Attach the HP tibial alignment verification rod and extension tube into the anterior aspect of the tibial pin guide.



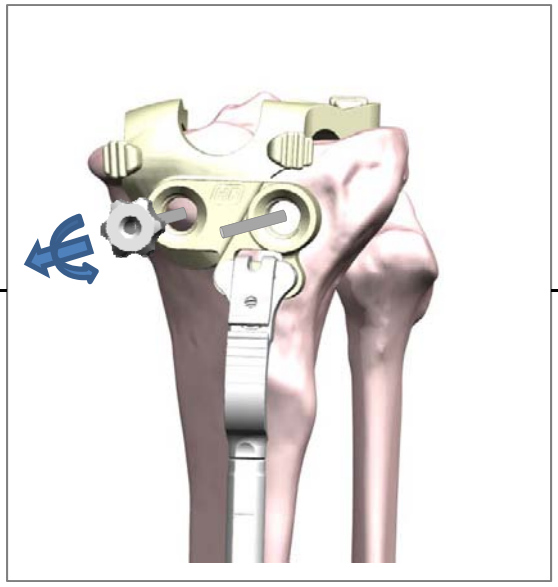
Step 3. Place the tibial pin guide onto the proximal aspect of the tibia while in flexion of approximately 90 degrees. Confirm proper orientation of the tibial pin guide using the alignment verification guide. The alignment verification guide should line up with the medial 1/3 of the tibial tubercle and be parallel to the axis of the tibia.



Step 4. Once in optimum position, secure the tibial pin guide by inserting one threaded 3.25 mm pin through each of the two anterior metal Fast-Guides.

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Basic TruMatch™ Surgical Steps – Tibial Preparation



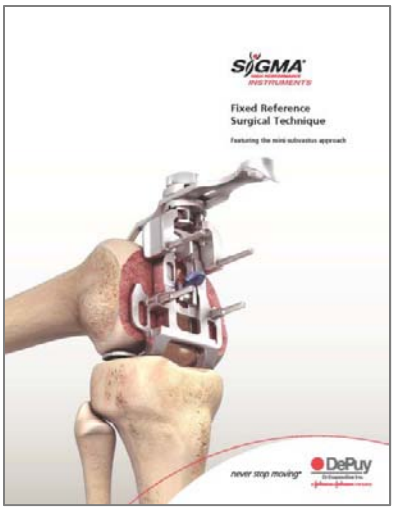
Step 5. With a counterclockwise twisting motion, remove the two Fast-Guides from the tibial pin guide. Remove the tibial pin guide while leaving the pins in place.



Step 6. Select the appropriate proximal tibial cutting guide from the HP instrument set. Perform the proximal tibial plateau resection in the standard manner.



Step 7. Introduce the spacer block and alignment rod. This may be helpful in assessing alignment and gap balance.



Step 8. Complete surgery following the steps of Sigma® High Performance (HP) Instruments, Fixed Reference Surgical Technique (Cat. No. 0612-87-510).

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Indications for Use:
The TruMatch Personalized Solutions system is intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.
The TruMatch Personalized Solutions system is intended for use with existing DePuy Orthopaedics, Inc. knee systems and their cleared indications for use.
The TruMatch Personalized Solutions system is intended for single use only.

Contraindications:
The following conditions are not compatible with the TruMatch Personalized Solutions:
• Previous knee replacement of the same knee.

Cautions:
•Any metal device that will cause scatter in the CT through the knee.
•Angular deformities greater than 15 degrees of fixed varus, valgus, flexion, or tibial slope exceeding 15 degrees.
•Moderate to severe bony deformities, charcot knee, or patients with severe patella tendon calcification that may prevent patella eversion.

For instruments produced by another manufacturer, reference the manufacturer's instructions for use.

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

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DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
USA
Tel: +1 (800) 366 8143
Fax: +1 (574) 267 7196

www.depuy.com

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EXHIBIT D:

WORK REQUESTS - BIOCOMPATABILITY

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

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EXHIBIT E:

WORK REQUESTS – PERFORMANCE TESTING

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R&D TEST REPORT

(b)(4) Testing

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

(b)(4) Testing

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Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

R&D TEST REPORT

SUBJECT: (b)(4) Testing CADAVER ACCURACY STUDY (b)(4) Testing

(b)(4) Testing

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

(b)(4) Testing

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Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

R&D TEST REPORT

SUBJECT: (b)(4) Testing DESIGN PROCESS AND DESIGN SOFTWARE REPEATABILITY STUDY

(b)(4) Testing

[redacted]

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

(b)(4) Testing

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Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

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

COVER SHEET MEMORANDUM

From: Reviewer Name Christina Beardsley

Subject: 510(k) Number K110397/S2

To: The Record

Please list CTS decision code SE

☐ 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%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold),

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes:

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NC	NSE call for PMAs
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
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)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
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)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank?* (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓

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Neonate/Newborn (Birth to 28 days)	
Infant (29 days -< 2 years old)	
Child (2 years -< 12 years old)	
Adolescent (12 years -< 18 years old)	
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.)	
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.* ✓

Regulation Number: 888.3560 Class*: II (*If unclassified, see 510(k) Staff) Product Code: JWH, OOG

Additional Product Codes: _____

Review: _____ (Branch Chief) JJPB (Branch Code) 8/16/2011 (Date)

Final Review: _____ (Division Director) 8/16/11 (Date)

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K110397/S002

Date: August 12, 2011
To: The Record
From: Christina Beardsley
510(k) Holder: DePuy Orthopaedics, Inc.
Device Name: DePuy TruMatch™ Patient Specific Instruments
Contact: Nancy Friddle, Project Manager, Regulatory Affairs
PO Box 988
700 Orthopaedic Drive
Warsaw IN 46581
Phone: (574) 371-4923
Fax: (574)371-4987
Email: nfriddle@its.jnj.com

Office: ODE
Division: DSORD/OJDB

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the DePuy TruMatch™ Patient Specific Instruments into interstate commerce. The proposed subject devices are patient-matched instruments indicated for use in the implantation of DePuy total knee arthroplasty devices (Sigma and Attune Knee Systems). Based on preoperative CT scans and preferences input by the surgeon, surgery is planned virtually by DePuy engineers and approved by the surgeon. The TruMatch guides are then created from the plan; some of the initial steps of the TKA implantation are performed with the sterile, disposable TruMatch pin guides or cutting guides, and the rest of the procedure is finished with traditional instrumentation.

The submission was initially placed on hold on February 18, 2011 because (b)(4) [redacted] As noted in the consulting review by Joseph Jorgens, III (OSEL/DESE), the additional information provided by the firm (added to file as S001/A001 in a document dated June 3, 2011) resolved all outstanding (b)(4) issues. Other factors contributing to the S001 telephone hold (on June 1, 2011) included (b)(4) [redacted] as well as other more minor areas of concern where additional information is warranted.

Miguel Ramirez, MD (OJDB) provided a clinical review of the submission in Supplement 002. (Earlier clinical input was provided informally in S001 by Elizabeth Panox-Adegboyega, MD (DSORD/OSDB)). Please see his attached memorandum for further comments. Dr. Ramirez notes that the TruMatch procedure, as clarified by supplemental information provided in Supplement 002, is similar to a procedure with traditional instruments. He did note (b)(4) (b) , including that (b)(4) [redacted] (b)(4) [redacted]

We discussed this issue further, and Dr. Ramirez acknowledges that most cases where this would be an issue occur where there is (b)(4) [redacted] is contraindicated in situations with moderate deformity or more; therefore, this is acceptable. Note, too, that if it appears to the surgeon

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(b)(4) Deficiencies

[redacted]

Because the sponsor supplemental information in S001/A001 which addresses all necessary (b)(4) [redacted] I recommend that the DePuy TruMatch™ Patient Specific Instruments be found substantially equivalent to predicate device-specific total knee arthroplasty instruments.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Prescription device) *Amended in S002 (page 00022 of S002)*	X		
Truthful and Accuracy Statement *On page 00010 in the original submission*	X		
510(k) Summary *Amended in S002 (page 00073 of S002)*	X		
Standards Form		x	

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)? *The device is not an implant, but it is an accessory to an implant and expected to affect its safe and effective use.*		X	
Does the device design use software?	X		
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

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The subject devices are sterile, single use instruments which are designed via information in preoperative imaging and intended to assist in positioning the distal femoral and proximal tibial cuts during total knee arthroplasty with DePuy implants (Sigma Fixed Bearing Implants and Attune Total Knee Implants). Trumatch™ Patient Specific Instruments are manufactured from RenShape® (b)(4) and stainless steel. They are marked with the patient name, patient date of birth, size and anatomy (right or left). There are two versions: cutting guides and pin guides. The cutting guides are like the pin guides, except (b)(4), whereas the pin guides use a (b)(4). After the initial pin placement (with the pin guides) or cutting (with the cutting guides) is performed with the TruMatch™ Patient Specific Instruments, standard instruments and trials are used to complete the knee implantation procedure.

As shown in Exhibit A, TruMatch (b) have a variety of catalog numbers, depending on the size and (left or right) side of the implant they are being used with. They may be packaged with both (b)(4) (b)(4),

The inside surfaces of the instruments are designed to (b)(4) (b)(4)

Because the device design is patient-specific (differs from patient to patient), it is not possible for the sponsor to describe the geometry and sizing of the device. In lieu of this, the appropriate device description is a detailed description of the design algorithm that is invoked for each patient, which the company should demonstrate is reproducible (not operator dependent), not changing the surgical goal, and results in positioning and orientation of the TKA implant which is comparable to that achieved with the traditional (i.e., non-patient-specific) instruments. A summary of the process is below:

DePuy describes the (b)(4) (b)(4)

In response to the S001 additional information, the sponsor provided (b)(4) (b)(4)

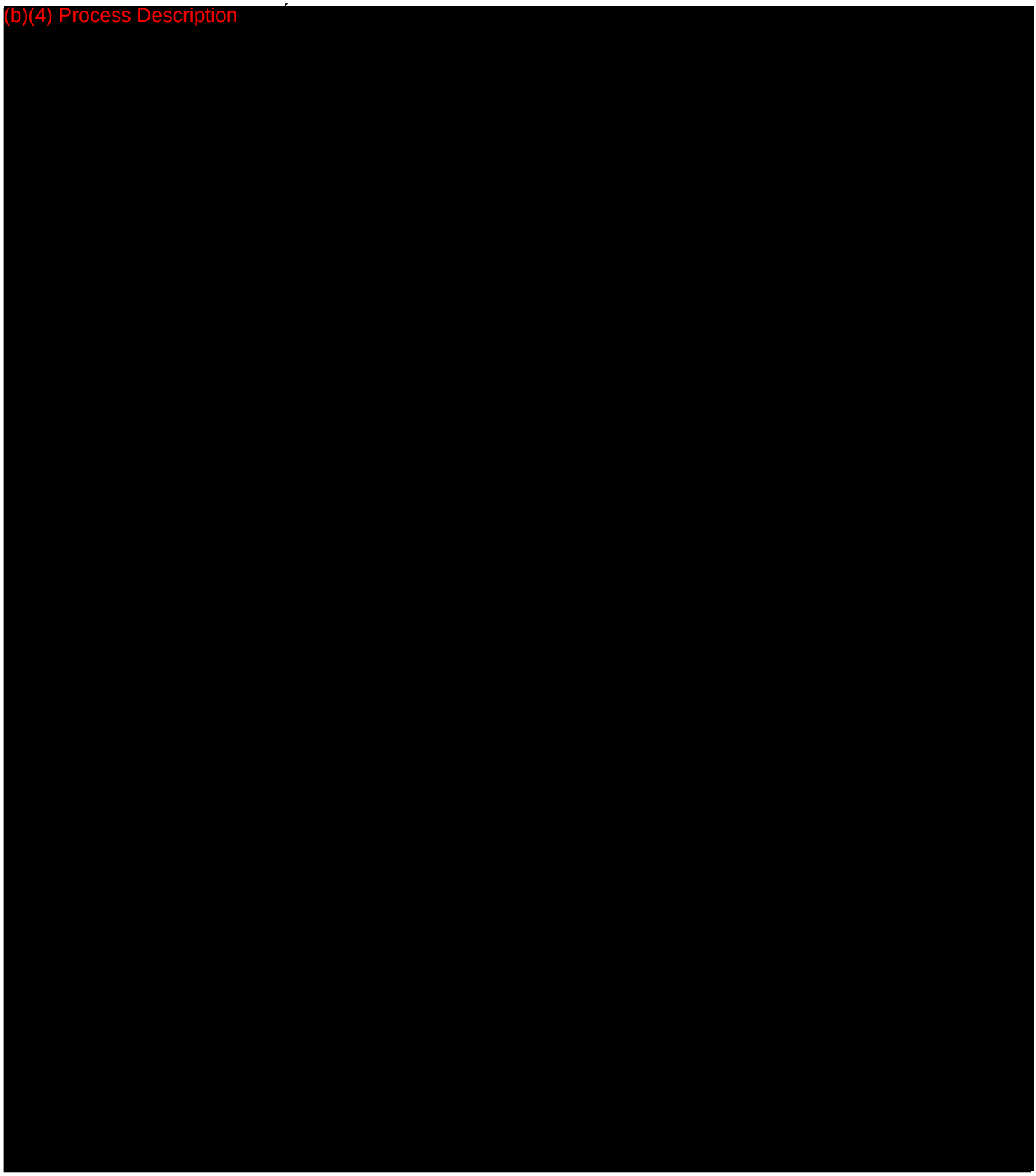
(b)(4)

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[redacted]

(b)(4) Process Description



Other patient-matched cutting guides also allow the user to choose from a variety of femoral landmark referencing options. However, the reasoning behind this is because different surgeons have different preferences/follow different technique within the practice of medicine. In the S001 additional information, DePuy was informed that their specification that the [redacted] (b)(4) Deficiencies

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(b)(4) Deficiencies

(b)(4) Deficiencies

This is acceptable.

(b)(4) Process Description

(b)(4) Process Description

(b)(4)

(b)(4)

(b)(4) Deficiencies

(b)(4)

(b)(4) Process Description

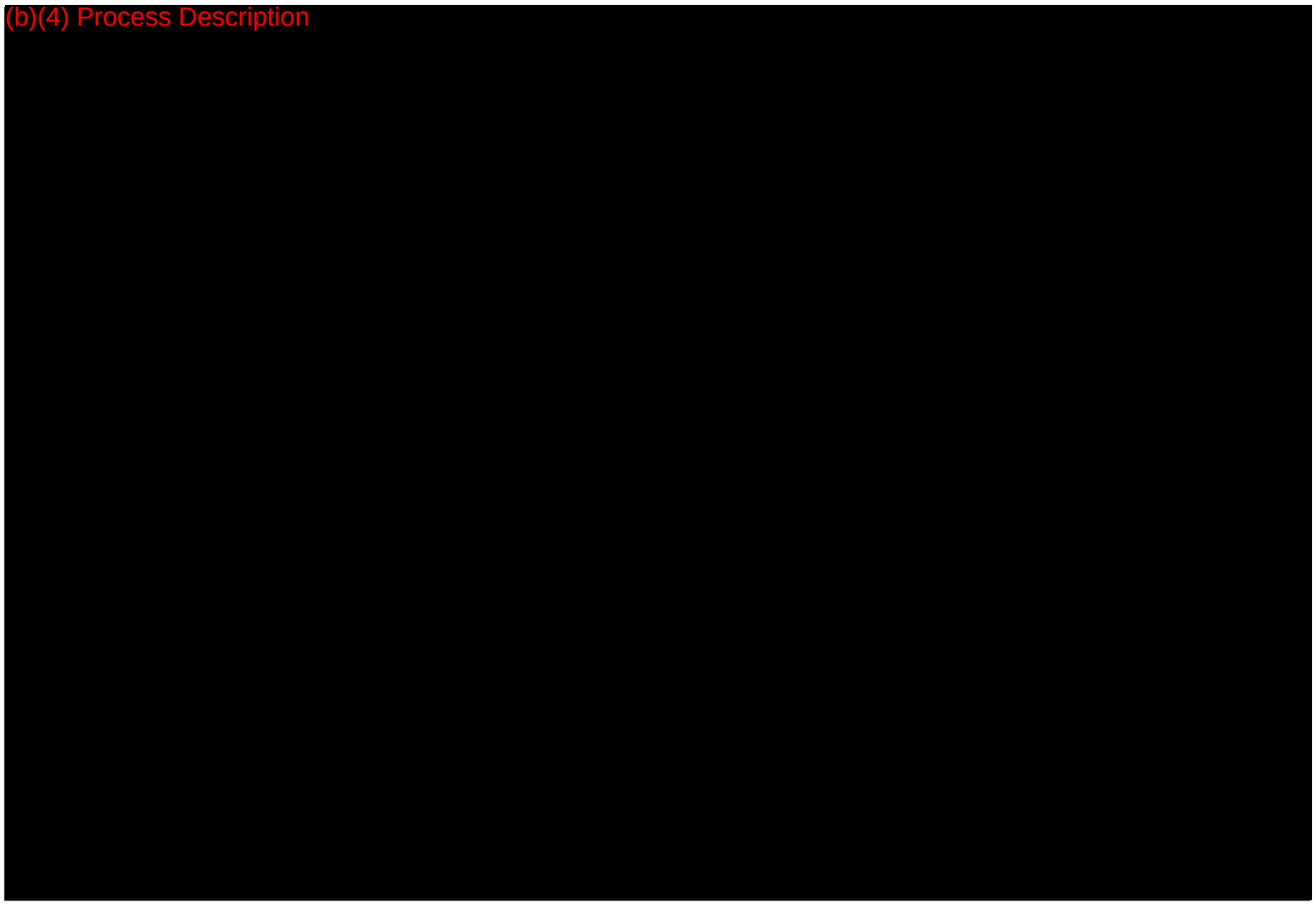
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

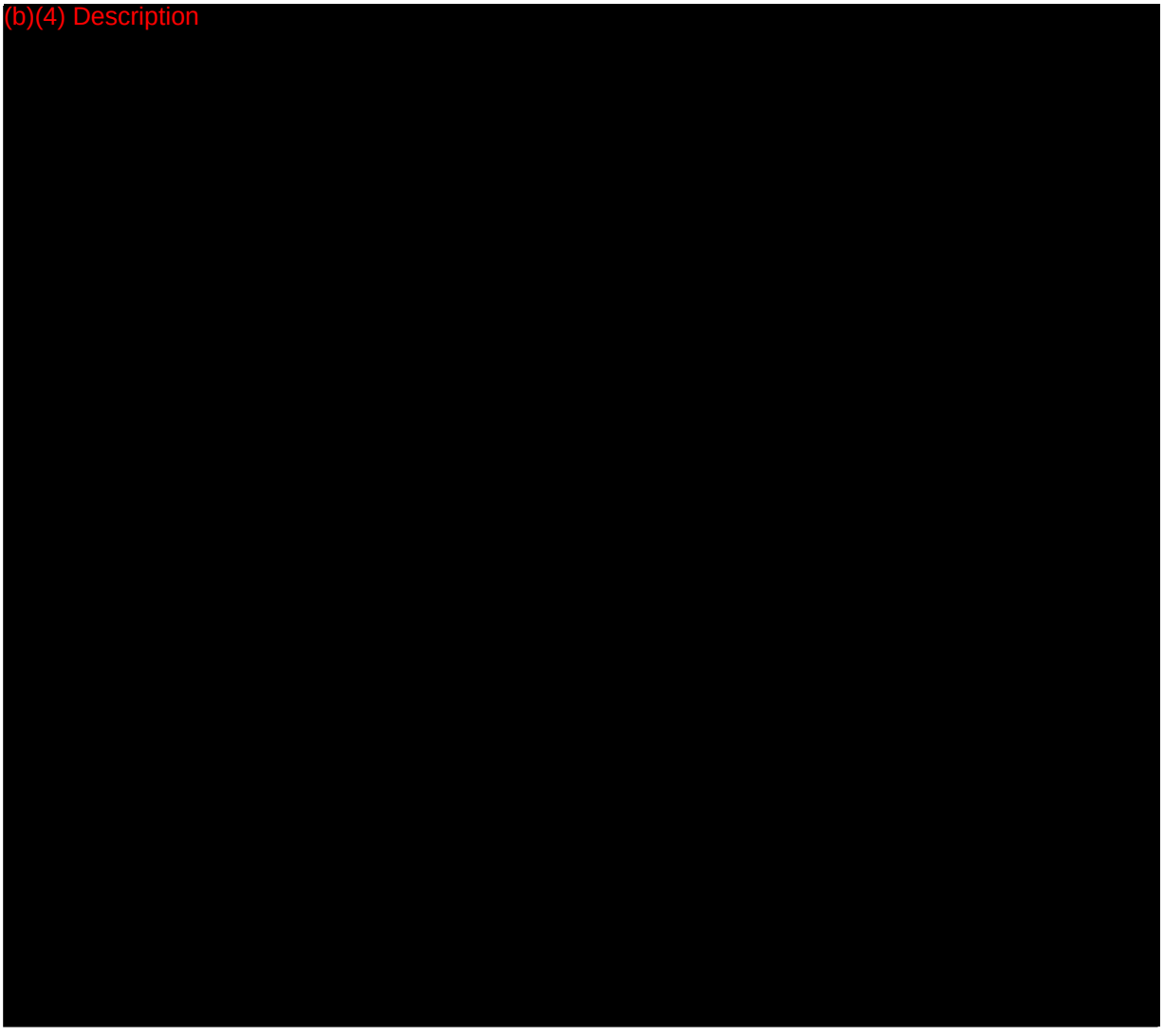
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(b)(4) Process Description



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(b)(4) Description



In S002 (Exhibit D), Depuy provided more complete definitions of each anatomical landmark/the systematic procedure by which each landmark is found should be given (e.g., how does the design engineer go about identifying the deepest part of the patellar groove anteriorly, etc.). Please see pages 00028-00031 of S002 for the procedures for (b)(4)

In S002 (Exhibit E), Depuy has more clearly defined (b)(4)

(b)

and has explained what each of the options is for some of these variables.

Anatomical landmark identification is by nature a subjective process, and even amongst surgeons, there is some variability in the precise point that would be identified as the particular landmark. Therefore, it is important to be as clear as possible when describing the method for locating anatomy of interest and the axis definitions that are based upon that anatomy. ***Dr. Ramirez believes that these definitions are acceptable.*** *Please see his memorandum for a more complete discussion of how these landmarks are identified in traditional TKA surgery versus the Trumatch procedure.*

In the original submission, it was also unclear (b)(4) Deficiencies

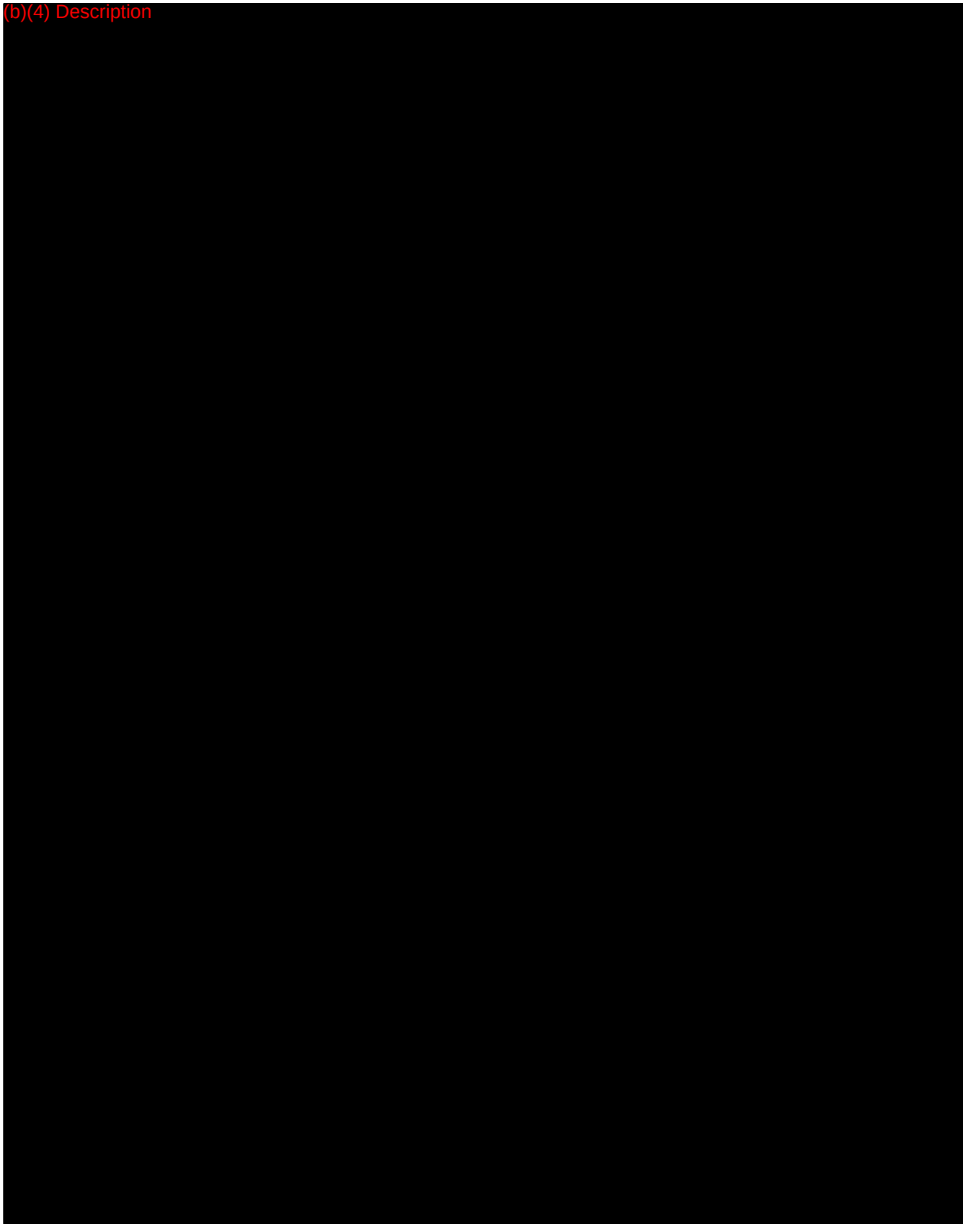
, the sponsor provided these data, and they were acceptable. (See 'Performance Testing – Bench' for further discussion).

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(b)(4) Description



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(b)(4) Description

[redacted]

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(b)(4) Description

[redacted]

Based on the description provided, Dr. Ramirez does not believe that the sponsor is changing basic principles of knee arthroplasty relative to TKA performed with traditional instruments.

IV. Indications for Use

The Indications for use (*updated in S002 (Attachment A) per FDA request*) are as follows:

"The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intraoperatively and in guiding the marking of bone before cutting.

The anatomical landmarks necessary for the creation of the TruMatch™ Patient Specific Instruments must be present and identifiable on CT.

The TruMatch™ Patient Specific Instruments are intended for use with Sigma® Total Knee Implants and Attune™ Total Knee Implants and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only."

The IFU now includes the specific DePuy knee systems that the instrument is to be used with. *Page 0009 of the original submission identifies these as the Sigma Total Knee System (cleared under various 510(k)s between 1988 and 2008) and the Attune Total Knee System (K101433).*

The instructions for use expound on the indications for use a bit, which is appropriate, and state that the subject device is for patients with osteoarthritis that meet the criteria for primary total knee replacement performed with a measured resection technique, who have mild bone deformities and/or angular deformities less than 15° of fixed varus/valgus or flexion, and do not have implants that cannot be kept away from the knee of interest during the CT scan. (It is acceptable for the patient to have hip, ankle, and/or soft tissue anchor implants). ***In S002, the company provided further explanation of how they concluded that hip, ankle, and soft tissue anchor implants were allowable and would not significantly affect accuracy of landmark identification****. The CT protocol highlights the importance of placing metallic implants as far from the affected knee as possible.*

In S002, in response to FDA comments in the S001 telephone hold, the sponsor added the stipulation to the indication that the device is only for use in patients where the appropriate landmarks are visible on CT. ***This is appropriate.***

V. Predicate Device Comparison

The predicate devices that the sponsor identifies are the Smith & Nephew Patient Matched Cutting Blocks (K082358).

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The Indications for use of the predicates are given below:

510(k) Number	Indications for use	Comments
K082358	Smith & Nephew's Patient Matched Cutting Blocks are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting. The Patient Matched Cutting Blocks are intended for use with existing Smith & Nephew, Inc. knee systems and their cleared indications for use.	*This indication is similar. Smith & Nephew did not list the specific knee systems that the guide is to be used with, but all subsequent systems have.* ***The sponsor should as well.***

The sponsor's performance data compare to their own system instruments, not to the Smith & Nephew predicate. ***The updated 510(k) Summary provided in S002 at FDA's request now makes it clear that this is how acceptance criteria were set and includes DePuy's traditional instruments as additional predicates.*** *The Smith and Nephew device, like the subject device, is also a patient-matched cutting guide for total knee arthroplasty and is an appropriate predicate.*

The sponsor's submission provides an overview comparing the basic surgical procedure steps for using the subject device versus the Smith & Nephew predicate (Table 2, original submission, pages 00018-00021), and for using the subject device versus their own traditional instrumentation (Table 3, original submission, pages 00022-00025).

Conceptually, the basic device design of the Smith & Nephew Patient Matched Cutting Blocks is similar to the design of the subject device. Although intended for use with Smith & Nephew knee systems instead of DePuy knee systems, this predicate does use 3D preoperative imaging of a hip to ankle scan to model the patient's anatomy, locate landmarks, construct mechanical axes, and plan a TKA procedure, based on input surgeon preferences for the case; it uses similar software packages to the TruMatch device as well; and it ultimately yields an approved surgical plan from which a patient-specific cutting guide is manufactured.

The Smith & Nephew predicate guide is made from nylon 12 (a.k.a. polyamide (b)(4)) material, whereas the subject device is made from stainless steel and RenShape (b)(4) To address this material difference from predicate devices, biocompatibility information is needed. This was supplied by DePuy. (See Section VIII of this memorandum for further details).

VI. Labeling

The sponsor has included labeling materials in Exhibit C of the original submission. This includes a draft package insert (updated in Exhibit M of S002), a surgical technique (updated in Exhibit F), and draft package labels. Labeling includes an appropriate prescription use statement (in the form of a symbol on the package label) as required by CFR 21.801.109(b)(1).

The outer package label includes the manufacturer's name and address and telephone number (*since this is manufactured abroad, it lists all this information for both DePuy International and DePuy Orthopaedics, Inc. (the US company)*), the device name and device size and model (left/right), a graphic depiction of the device, the patient's name, the patient's date of birth, the surgeon's name, the knee system that it is intended for use with, the materials, the expiration date, catalog and batch numbers, and indicates that the device is sterilized by irradiation and single use. The package also indicates not to use the device if the package is damaged and to see the instructions for use. There are symbols on the label, but the same information is also conveyed in text on a separate package label (*this meets ODE requirements*).

The instructions for use in the package insert describe the device, stating that it is provided sterile and if the package is damaged, it should not be used, because it cannot be resterilized. It gives some

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information on patients who the device is intended for (those with osteoarthritis that meet the criteria for primary total knee replacement performed with a measured resection technique, who have mild bone deformities and/or angular deformities less than 15° of fixed varus/valgus or flexion, and do not have implants that cannot be kept away from the knee of interest). Instructions for use also include indications, contraindications (previous knee replacement of the same knee; *this is appropriate, as anatomy necessary to create the guide has been resected and/or may be obscured by metal artifact*), and cautions. The cautions include:

- Any metal device that will cause scatter in the CT throughout the knee
- Angular deformities greater than 15 degrees of fixed varus, valgus, flexion or tibial slope exceeding 15 degrees
- Moderate to severe bony deformities, Charcot knee, or patients with severe patella tendon calcifications that may prevent patella eversion

An updated surgical technique was provided in Exhibit F of S002. The surgical technique includes pictures and text description. It clearly illustrates all steps of the technique and how the subject device is used during the procedure. It also states that use of the TruMatch represents an addendum to the technique with uses the Sigma High Performance (HP) instruments, and that the surgeon must be familiar with the use of the Sigma HP instruments, as these are required in steps prior to, and following, the utilization of the TruMatch guides. Along with the guides, the surgeon is sent the Patient Proposal (i.e., the surgical plan) which shows views of the guide relative to the segmented patient anatomy, to help the surgeon position the guide correctly. On the tibial side, an alignment adapter and rod are used to help verify that the cut the guide would produce is appropriate. According to the technique, the guide should not have to be forced to seat properly, and when in its optimum position, it should not toggle or rock. The technique notes that if it is necessary to adjust ligament tension, the distal aspect of the femur or the proximal aspect of the tibia can be re-cut to achieve proper balance, using the regular HP instrument cutting/resection guides, which fit over the pins placed by the TruMatch instruments. *The surgical technique in the original submission indicated that the surgeon may request resection of impinging osteophytes for proper block placement and fit. This is potentially problematic, as it is not clear how planning software would be able to simulate with sufficient accuracy what the geometry of the knee will be post-osteophyte removal; osteophyte removal is a manual task/matter of surgeon judgement are therefore may likely be difficult to reproduce. The "Surgical Tips and Pearls" section of the technique also indicated that it is the TruMatch design team that may make requests for the surgeon to remove osteophytes (highlighted in red in the patient proposal). When this point was raised to the sponsor in the S001 telephone hold (item 1g), the sponsor responded by saying that "Osteophyte removal was needed with the first generation TruMatch™ device due to the limitations of that manufacturing process. DePuy has since discontinued the first generation device and that manufacturing process. The TruMatch™ device included in this 510(k) submission does not require the need for osteophyte removal." This ameliorates concerns about the guide not fitting due to manual osteophyte removal.*

The original surgical technique also stated that "it is not uncommon to see a 2-3 mm gap around the periphery of the guide due to cartilage loss." Gap is allowed, but toggle is not. It notes, too, that after the femoral resection, if there is evidence of damage by the saw blade on the posterior aspect of the cutting block, the condyle cut was likely undercut and out of plan (the block can be repositioned and the cut repeated in this instance).

The sponsor has included a 510(k) Summary. It was amended in S002. ***The amended document is acceptable.*** *This document does list all systems that the TruMatch instruments can be used with. It identifies predicate devices, has the appropriate primary and secondary product codes, as well as the updated indications, and appears to meet the requirements of 21 CFR 807.92.*

The indications for use in the 510(k) Summary and throughout the labeling matches the indications on the IFU form verbatim.

VII. <u>Sterilization/Shelf Life/Reuse</u>

TheTruMatch™ Patient Specific Instruments are sterilized using (b)(4) [redacted]

(b)(4) [redacted]

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[redacted]

According to DePuy, the subject device is packaged in a (b)(4) and sealed with a (b)(4) lid. *These packaging materials are appropriate for a* (b)(4). DePuy states that the packaging system for the TruMatch has been validated for an 11-year shelf life. (b)(4)

[redacted]

(b)(4)

Therefore, this is acceptable.

The devices are not labeled as pyrogen free and the company has conducted pyrogen testing. *Based on OJDB historical practice, sponsors have not been required to submit pyrogenicity testing for review, even for implant devices, unless they are making a pyrogen-free claim in the labeling.*

VIII. Biocompatibility

In Exhibit D, DePuy provided (b)(4) tests on the (b) Renshape (b)(4) material that was conducted by (b)(4). The test article for all tests was Renshape (b)(4), produced via (b)(4) sterilized.

Test	Summary of methods/results
(b)(4)	[redacted]

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(b)(4) Testing

[redacted]

The tests performed include the FDA-recommended ISO10993 evaluations for devices which have limited duration contact with a breached surface (including (b)(4) Testing (b)(4) (b)(4) Testing *Results were acceptable. Therefore, there are not concerns that the biocompatibility of the will not be substantially equivalent to predicate devices.*

The other material in the subject device is (b) stainless steel. In S002 (Exhibit J), DePuy provided information about the conformance of this material to recognized standards, specifically ASTM F899-09: *Standard Specification for Wrought Stainless Steels for Surgical Instruments. This is acceptable for purposes of biocompatibility.*

IX. Software

The sponsor explains that TruMatch™ Software consists of the TruMatch™ TeamCenter Surgeon Interface and the TruMatch™ Design Software. The TruMatch™ TeamCenter Surgeon Interface is a web page that will be used by surgeons to securely configure surgical preferences, review patient proposals, request patient proposal modifications and approve patient proposals. The TruMatch™ Design Software is a compilation of OTS software tools (Amira or Mimics, Geomagic, Unigraphics NX) that are used in-house by trained Design Operators to create TruMatch™ Patient Specific Instruments.

Joseph Jorgens, III (Senior Biomedical and Software Engineer, OSEL/DESE) provided a consulting review for the device software documentation, which was provided in S001, and of the additional information submitted to the file on June 3, 2011. As discussed by Dr. Jorgens in his attached memorandum (dated July 1, 2011), the outstanding issues related to the (b)(4) (b)(4) have been resolved, and **the software documentation is complete.**

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

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Not applicable.

XI. Performance Testing -- Bench

(b)(4)

[redacted]

(b)(4)

Testing submitted by DePuy is summarized below:

TruMatch™ Dimensional Stability Testing

(b)(4)

[redacted]

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(b)(4)



Cadaver Accuracy Study

(b)(4)



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(b)(4) Testing

(b)(4) Testing

[redacted]

As shown in Table 7 above, the sponsor has concluded that the results of the cadaver validation were acceptable. The Specialist II data upon which the acceptance criteria are based were provided in S002 (Exhibit H).

There was a question in initial review of the data as to whether or not the (b)(4) [redacted] (b)(4) *. This is reasonable.*

(b)(4) Testing

[redacted]

TruMatch™ Design Process and Design Software Repeatability Testing

(b)(4) Testing

[redacted]

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(b)(4) Testing

No animal performance testing was provided in this submission.

XIII. Performance Testing – Clinical

No clinical testing was provided in this submission. Clinical data are not needed to establish substantial equivalence. (b)(4) Testing [redacted]

I consulted with Mark Melkerson (Division Director, DSORD) about this information, as I was not sure if per least burdensome requirements, I should ask DePuy about these trials. After speaking with Mr. Melkerson, I called DePuy on August 10 to discuss this information and asked them to confirm that they (b)(4) Testing [redacted] *Via email on August 12, 2011 (attached), DePuy made this confirmation.*

XIV. Substantial Equivalence Discussion

	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?		X	If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	X		If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	x		Final Decision: SE

1. Explain how the new indication differs from the predicate device's indication:
The indications for use for the subject device convey a similar intended use as the indications of the predicate knee system instrumentation, but there is a caveat which restricts use to situations under which the anatomy is identifiable. The subject device is for use with the sponsor's own knee systems, not the predicate firm's knee systems.

2. Explain why there is or is not a new effect or safety or effectiveness issue:
The difference in indication does not alter the effect or raise new types of safety and effectiveness questions because the indication is a slightly narrower subset of the population which is indicated for the

predicate device. This is not a situation where general to specific issues apply. The caveat on identifiable anatomy will likely improve safe and effective use of the device.

3. Describe the new technological characteristics:
The subject device is similar in intended use to the predicate device and, like the predicate, uses software and imaging to match the device to the patient. However, unlike the predicate, the subject device has a new material (Renshape). The patient-matching algorithm and software programs used are similar to the predicate, but not identical.

4. Explain how new characteristics could or could not affect safety or effectiveness:
Implementation of a new patient-matched design process could systematically or sporadically produce different final implant placement and orientation, potentially affecting the performance and survivorship of the associated total knee arthroplasty. New materials can affect safety and effectiveness if they do not have sufficient biocompatibility for limited duration contact with bone tissue and or if they are not able to maintain performance (dimensional and mechanical integrity) after sterilization.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
The questions are not new types of questions. All patient-contacting materials need to be biocompatible. All instrument systems for total knee arthroplasty, whether patient matched or not, if poorly designed or difficult to use, carry the risk of adversely affecting implant placement and performance. All devices with software require adequate software documentation.

9. Explain how the performance data demonstrate that the device is or is not substantially equivalent:
The sponsor has provided biocompatibility data on sterilized samples of the processed device material, which show that it passes cytotoxicity, sensitization, and intracutaneous reactivity. In addition, the sponsor has provided thorough description of the design process and how its risks, and those of the associated software packages used in the process, are controlled. This information also shows that the operating surgeon has adequate input into the final device design. Moreover, repeatability testing across design engineers and cadaver testing involving multiple specimens was invoked to characterize the expected sources of variability in the process, and the sponsor compared the cadaver results directly to the variability in cadaveric implantation of the same total knee devices with traditional instruments.

XV. Deficiencies
There are no remaining deficiencies.

XVI. Contact History
07-27-11 I received a voicemail from Ms. Friddle, who was checking on the status of the review. I left her a voicemail message on 08-01-11 informing her that the submission was still under review, but that all of the software documentation issues had been resolved.

08-10-11 After a series of phone messages back and forth between FDA and DePuy over several days, I spoke with Nancy Friddle. I asked her about the (b)(4) of the subject device noted on (b)(4) (b)(4) Deficiencies [redacted]

08-11-11 Additional information received via email from DePuy (attached), (b)(4) Deficiencies [redacted]

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

08-12-11 Nancy Friddle replied via email (attached), indicating that DePuy (b)(4) Deficiencies (b)(4) Deficiencies

XVII. Recommendation

Because the sponsor has provided supplemental information which addresses all necessary software documentation for this device, the device description and labeling suggests that the TruMatch follows the same principles of total knee arthroplasty as traditional (non-patient-matched) cutting guides, the cadaver testing indicates comparability variability in positioning and orientation to traditional knee instrumentation, the repeatability testing indicates that the design engineer performing the operation does not contribute significant variability to the process, and the limited duration contact biocompatibility tests passed, I recommend that the subject device be found substantially equivalent to predicate devices.

Regulation Number: 21 CFR 888.356
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH, OOG

Christina L Beardsley

Christina Beardsley, PhD Reviewer — Date 8/12/11

Acting Branch Chief — Date 8/16/2011

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Beardsley, Christina

From: Friddle, Nancy [DPYUS] (b)(4)
Sent: Thursday, August 11, 2011 7:57 AM
To: Beardsley, Christina
Importance: High
Attachments: FDA August Reponse 11-Aug-2011.doc

Dr. Beardsley---here are responses to the two questions that we discussed via phone call yesterday regarding the TruMatch 510(k) (K110397). I will be out of the office today but will check email this evening and will be back in tomorrow. Please let me know if you have any questions regarding these responses. Thanks for your continued assistance with this review.

Regards,

Nancy

Nancy Friddle
Project Manager, Regulatory Affairs
DePuy never stop moving
DePuy Orthopaedics, a J&J Company
PO Box 988 Tel: (574) 267-8143
700 Orthopaedic Drive Direct: (574) 371-4923
Warsaw, IN 46581-0988 Fax: (574) 371-4987
USA Email: (b)(4)
The above information is intended only for the person or entity to whom it is addressed and may contain confidential and/or privileged information. Any review, retransmission, dissemination of, or taking of any action in reliance upon, this information by others than the intended recipient is prohibited. If you are not the intended recipient, please return this email to the sender and delete it from any computer.

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

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Beardsley, Christina

From: Beardsley, Christina
Sent: Thursday, August 11, 2011 8:09 AM
To: 'Friddle, Nancy [DPYUS]'
Subject: RE:

Thank you for the very prompt reply. This should be sufficient to address these two points. Could you also respond to confirm, as discussed yesterday, that DePuy does (b)(4) Deficiencies [redacted] supplied in the 510(k)?

Kind regards,
Christina

From: Friddle, Nancy [DPYUS] [mailto(b)(4) [redacted]]
Sent: Thursday, August 11, 2011 7:57 AM
To: Beardsley, Christina
Subject:
Importance: High

Dr. Beardsley---here are responses to the two questions that we discussed via phone call yesterday regarding the TruMatch 510(k) (K110397). I will be out of the office today but will check email this evening and will be back in tomorrow. Please let me know if you have any questions regarding these responses. Thanks for your continued assistance with this review.

Regards,

Nancy

Nancy Friddle
Project Manager, Regulatory Affairs


DePuy Orthopaedics, a J&J Company
PO Box 988 Tel: (574) 267-8143
700 Orthopaedic Drive Direct: (574) 371-4923
Warsaw, IN 46581-0988 Fax: (574) 371-4987
USA (b)(4) [redacted]
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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 # 2016-626; Released by CDRH on 11-01-2016

Beardsley, Christina

From: Friddle, Nancy [DPYUS] (b)(4)
Sent: Friday, August 12, 2011 11:36 AM
To: Beardsley, Christina
Subject: K110397
Importance: High

Dr. Beardsley—following is a response to your request for information regarding the clinical data:

(b)(4) Deficiencies

Please let me know if you have further questions.

Hope your weekend is good and that it doesn't go too quickly!:)

Nancy

Nancy Friddle
Project Manager, Regulatory Affairs

DePuy never stop moving

DePuy Orthopaedics, a J&J Company

PO Box 988 Tel: (574) 267-8143
700 Orthopaedic Drive Direct: (574) 371-4923
Warsaw, IN 46581-0988 Fax: (574) 371-4987
USA Email: (b)(4)

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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 # 2016-626; Released by CDRH on 11-01-2016

MEMO OF

SOFTWARE REVIEW

of a MODERATE Level Of Concern device

510(k): K110397/S001/A001

DATE: 7/1/11

FROM: Joseph Jorgens III, Senior Biomedical and Software Engineer OSEL-DESE 301-796-2588

TO: Christina Beardsley ODE/DSORD/OJDB Bldg 66 1506 301-796-6404

SUBJECT: Software review of DePuy Orthopedics's TruMatch Patient Specific Instruments. 700 Orthopaedic Drive, Warsaw, Indiana. Contact: Nancy Friddle, Project Manager, Regulatory Affairs: 574-371-4923.

Succinct Conclusion: S.E.

The information contained within this submission is sufficient to meet the software concerns as described in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, and it is recommended that, from a software standpoint, this submission be considered substantially equivalent.

SUMMARY:

The TruMatch Patient Specific Instruments are single-use devices that are preoperatively designed to assist in the positioning of a joint replacement component intra-operatively and in guiding the distal femoral and proximal tibial cuts for a particular patient. A TruMatch Patient Specific Instrument set includes a proximal tibial and distal femoral device. [redacted] to the patient's distal femur and proximal (b)(4) [redacted] (b)(4)

TruMatch Patient Specific Instruments have two variants: [redacted] (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted] During surgery, after initial cuts or pin placements with the TruMatch

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Patient Specific Instruments are made, standard instruments and provisionals (trials) are used to complete the surgery. TruMatch Patient Specific Instruments are manufactured from RenShape (b)(4))(4) and stainless steel. Stainless steel saw captures and drill bushings are used to produce accurate bone cuts and drill holes. The TruMatch Patient Specific Instruments are designed to be used with Sigma Fixed Bearing Implants and the Attune Total Knee Implants:

1. Sigma CR Femoral components
2. Sigma CR150 Femoral components:
3. Sigma PS Femoral components
4. Sigma Standard FB Tibial Trays:
5. Sigma Modular FB Tibial Tray
6. Sigma Modular Plus FB Tibial Tray
7. Sigma Fixed Bearing Stabilized Inserts
8. Sigma Fixed Bearing Curved Inserts
9. Sigma Fixed Bearing PLI Inserts
10. Sigma Cruciate Retaining All Poly Tibia
11. Sigma Cruciate Retaining Posterior Lipped All Poly Tibia
12. Sigma Cruciate-Substituting All Poly Tibia
13. Attune Total Knee Implants

(b)(4)

Step Description

(b)(4)

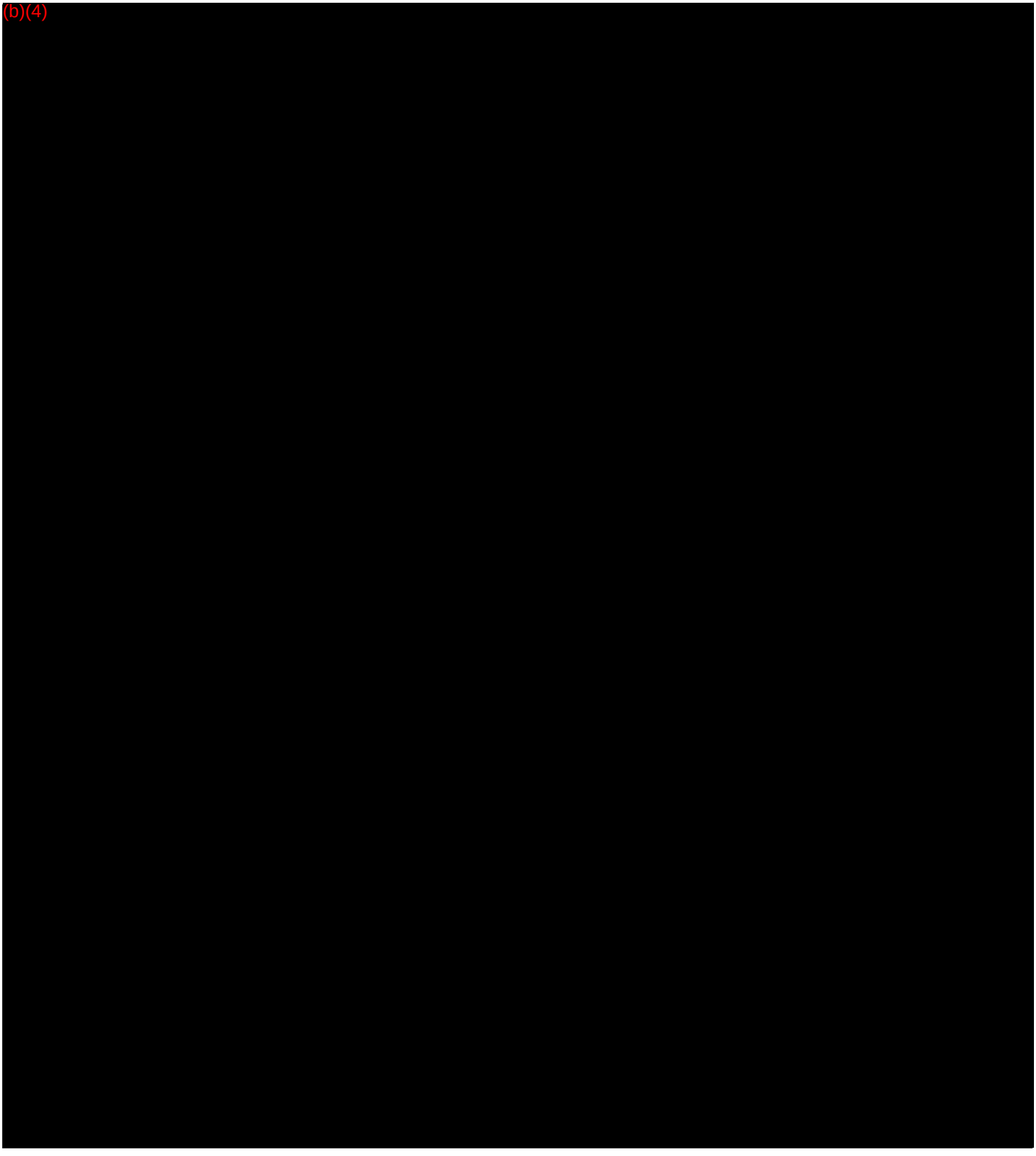
(b)(4)

(b)(4)

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4)



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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4)

[redacted]

Software Controlled Aspects of the Device

All components of the device are controlled/monitored by software, which is responsible for the functionality, user interface, safety checks and performance accuracy.

SOFTWARE REVIEW

1. **Level of Concern: Acceptable**
In the Supplement, in Section 1 entitled Level of Concern, the firm provided the correct determination of the Level Of Concern and included their supporting rationale: MODERATE.

2. **Software Description: Acceptable**
In the original submission beginning in the Section entitled Device Description and in S001 in Exhibit D entitled System Architectural Design Document, the firm provided an acceptable overview of the device features that are controlled by software, and a description of the intended operational environment, which includes information on the programming language, the hardware platform and the operating system.

3. **Device (including software) Hazard Analysis: Acceptable**
In A001 to S001, in Section entitled Exhibit A1 and A2 - Software Hazard Analysis, the firm provided an acceptable description of the hazards presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards.

4. **Software Requirements Specifications (SRS): Acceptable**
In the Supplement, in the Section entitled Software Requirements, the firm provided an acceptable copy of the Software Requirements Specification document, which documented the functional, performance, interface, design and development requirements.

5. **Architecture Design Chart: Acceptable**
In the Supplement, in the document entitled Software Architecture, the firm provided an acceptable detailed depiction of functional units and software modules, which included state diagrams as well as flow charts.

6. **Software Design Specification (SDS): Acceptable**
In A001 to S001, in Section entitled Exhibit B entitled Software Design Document, the firm provided an acceptable Design Specification Document, which describes how the requirements in the Software Requirements Specifications (SRS) are implemented.

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

7. **Traceability: Acceptable**
In A001 to S001, in the Section entitled Exhibit C Software Traceability Analysis, the firm provided an acceptable traceability matrix, which provides traceability among identified hazards and mitigations, requirements, specifications, and verification and validation testing.

8. **Software Development Environment Description: Acceptable**
In A001 to S001, in the Section entitled Exhibit D – Software Development Plan, the firm provided an acceptable description of the software development environment, which included a summary of the software life cycle development plan, and a summary of the configuration management and maintenance activities.

9. **Verification and Validation Documentation: Acceptable**
In A001 to S001, in the Sections entitled Exhibits E, F, G, H, and I concerning V and V, the firm provided an acceptable description of the validation and verification activities at the unit, integration and system level, which included system level test protocols, including the pass/fail criteria, and the results of these activities

10. **Revision Level History: Acceptable**
In the Supplement, in Appendix C, entitled Software Release Level, the firm provided an acceptable revision history log, which provides the history of software revisions generated during the course of product development.

11. **Unresolved Anomalies (Bugs or Defects): Acceptable**
In A001 to S001, in the Section entitled Appendix A in Exhibit I, firm provided an acceptable list of the remaining software anomalies, annotated with an explanation of the impact of the anomaly on safety or effectiveness, including operator usage and human factors.

12. **Information Security: Acceptable**
In A001 to S001, in the Section entitled Exhibits J – Cyber and Information Security, the information security issues were acceptably addressed.

RECOMMENDATION: SUBSTANTIALLY EQUIVALENT

The firm has provided acceptable documentation demonstrating that they have developed the software for this device under an appropriate software development program; that they have performed a hazard analysis from both the patient's and user's standpoint, and addressed those hazards; and carried out an appropriate validation process. These procedures provide the foundation for assuring, to the extent possible, that the software will operate in a manner described in the specifications, and in no other way. It is recommended that from a software standpoint this submission be considered substantially equivalent.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8718

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Division of Surgical, Orthopedic and Restorative Devices

Food and Drug Administration
Office of Device Evaluation
Center for Devices and Radiological Health

Date: 7/11/2011
To: Christina Beardsley, Lead Reviewer, DSORD/OJDB /ODE

CC:
From: Miguel A. Ramirez, MD, Medical Officer, OJDB/DSORD/ODE

Subject: **K110397:** DePuy TruMatch™ Patient Specific Instruments
Product Code: DePuy TruMatch™ Patient Specific Instruments
Sponsor: DePuy Orthopaedics, Inc.

Contact:

K110397

Scope of Review
This Memo reviews submission **K110397** which pertains to the DePuy TruMatch™ Patient Specific Instruments. The purpose of this consultation is to provide clinical insight into the product in regards to its safety and effectiveness.

Background and Regulatory History

The 510(k) holder would like to introduce the DePuy TruMatch™ Patient Specific Instruments into interstate commerce. The proposed subject devices are patient-matched instruments indicated for use in the implantation of DePuy total knee arthroplasty devices (Sigma and Attune Knee Systems). Based on preoperative CT scans and preferences input by the surgeon, surgery is planned virtually by DePuy engineers and approved by the surgeon. The TruMatch guides are then created from the plan; some of the initial steps of the TKA implantation are performed with the sterile, disposable TruMatch pin guides or cutting guides and the rest of the procedure is finished with traditional instrumentation.

Reviewer Comments:
It is the opinion of this reviewer that the sponsor has addressed several of the safety and effectiveness concerns previously raised. However, there are still some issues that in the opinion of this reviewer should be addressed prior to approval. In summary, some of these are:

40

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

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(b)(4) Deficiencies

[redacted]

Device Description

The subject devices are sterile, single use instruments which are designed via information in preoperative imaging and intended to assist in positioning the distal femoral and proximal tibial cuts during total knee arthroplasty with DePuy implants (Sigma Fixed Bearing Implants and Attune Total Knee Implants). Trumatch™ Patient Specific Instruments are manufactured from RenShape® (b)(4)) and stainless steel. They are marked with the patient name, patient date of birth, size and anatomy (right or left). There are two versions: cutting guides and pin guides. The cutting guides are like the pin guides, [redacted] (b)(4) (b)(4) After the initial pin placement (with the pin guides) or cutting (with the cutting guides) is performed with the TruMatch™ Patient Specific Instruments, standard instruments and trials are used to complete the knee implantation procedure.

(b)(4)

[redacted]

A summary of the process is below:

DePuy describes the process [redacted] (b)(4)

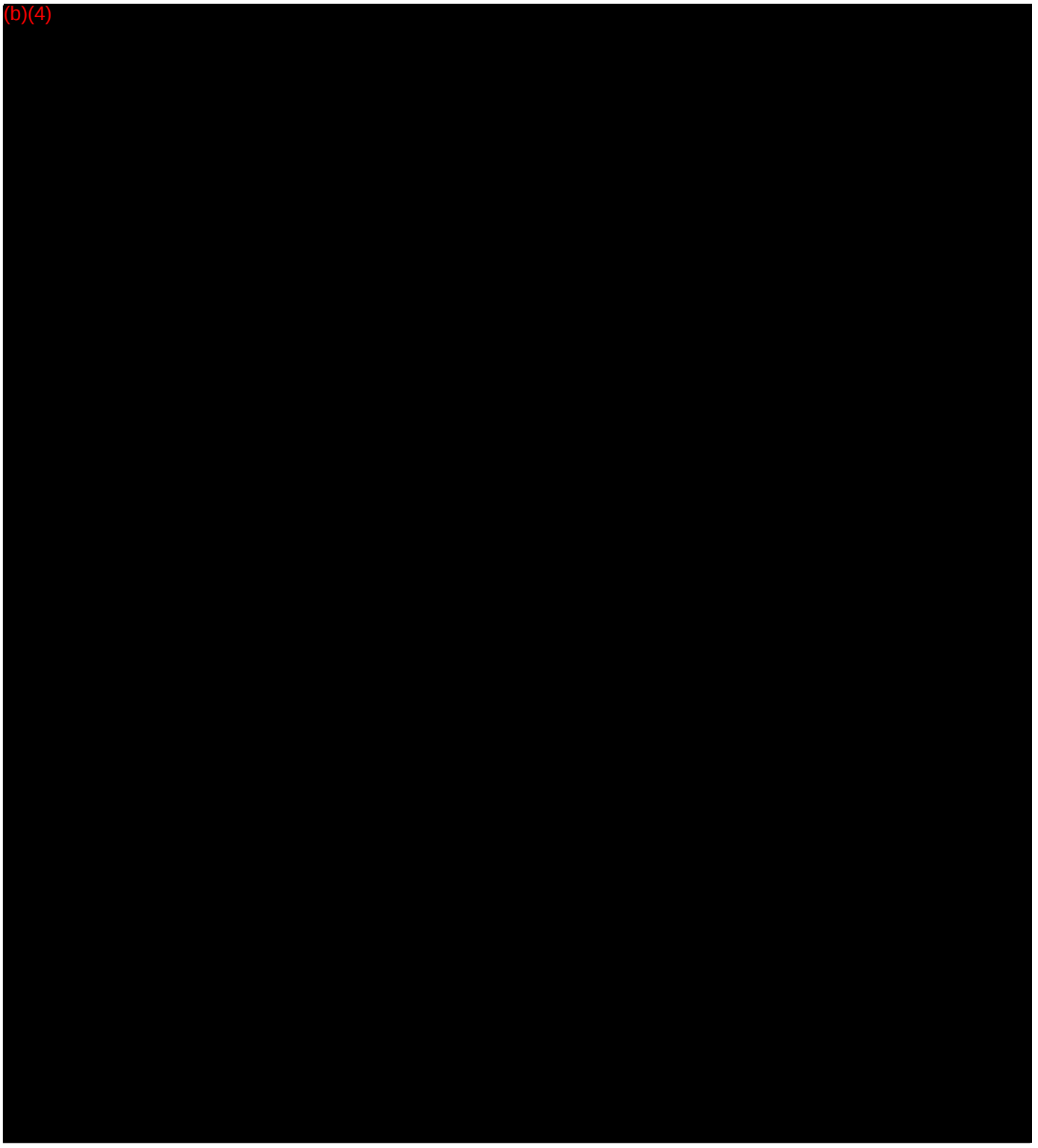
[redacted]

41

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4)



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

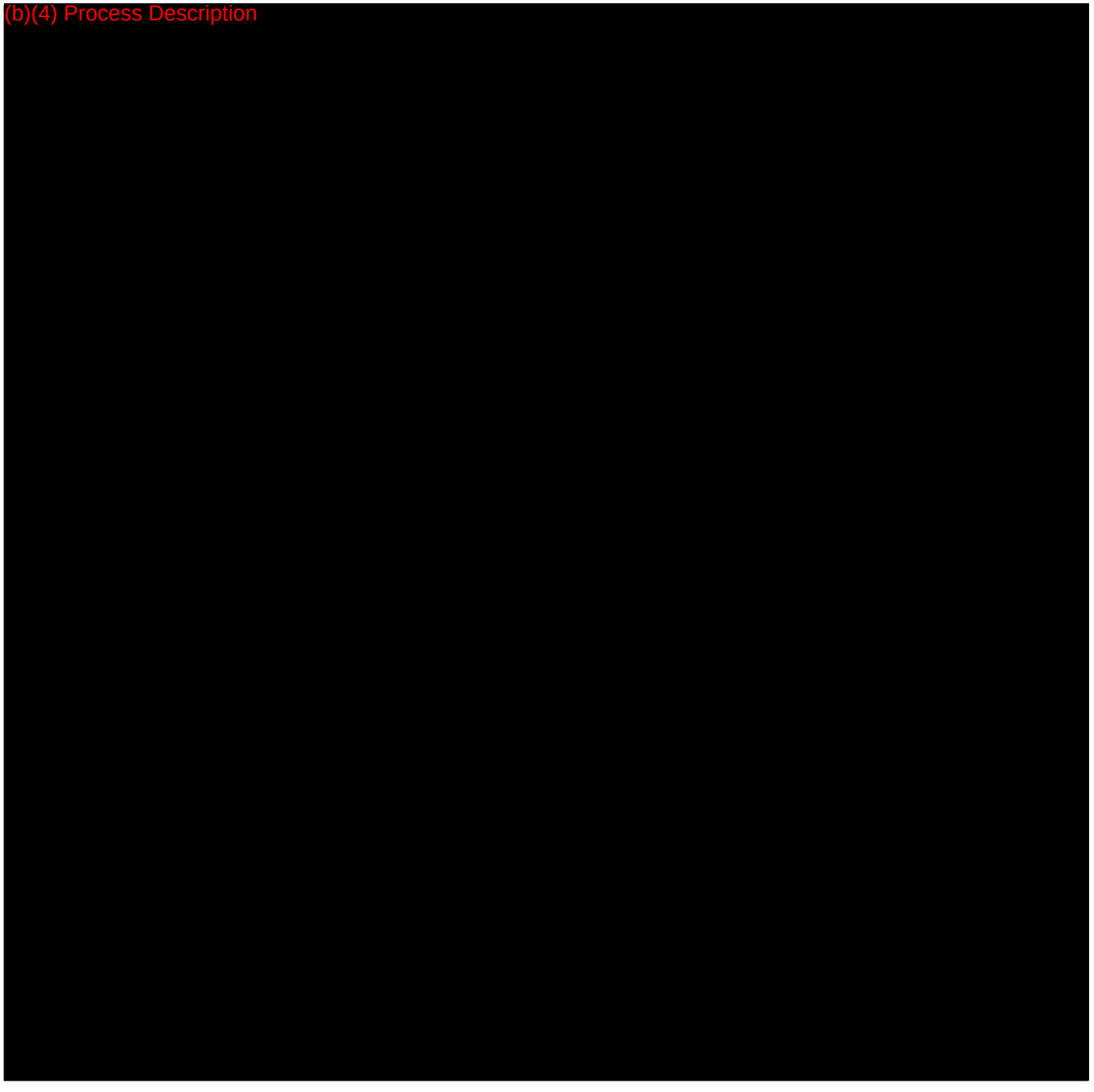
Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Landmark	Description	Definition	Review
(b)(4)			

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4) Process Description



Indications

The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intraoperatively and in guiding the marking of bone before cutting.

The anatomical landmarks necessary for the creation of the TruMatch™ Patient Specific Instruments must be present and identifiable on CT.

The TruMatch™ Patient Specific Instruments are intended for use with Sigma® Total

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Knee Implants and Attune™ Total Knee Implants and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only

Technical Information and Analysis

This device raises significant concerns regarding patient safety. Most of the concerns are related to [redacted] (b)(4)

(b)(4)

(b)(4) Deficiencies

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

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4) Deficiencies

[redacted]

Miguel A. Ramirez, MD,
Medical Officer, OJDB/DSORD/ODE

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

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

COVER SHEET MEMORANDUM

From: Reviewer Name Christina Beardsley

Subject: 510(k) Number K110397/S1

To: The Record

Please list CTS decision code TH

☐ 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)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? 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)			
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			
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)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
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.)			

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

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

Additional Product Codes:

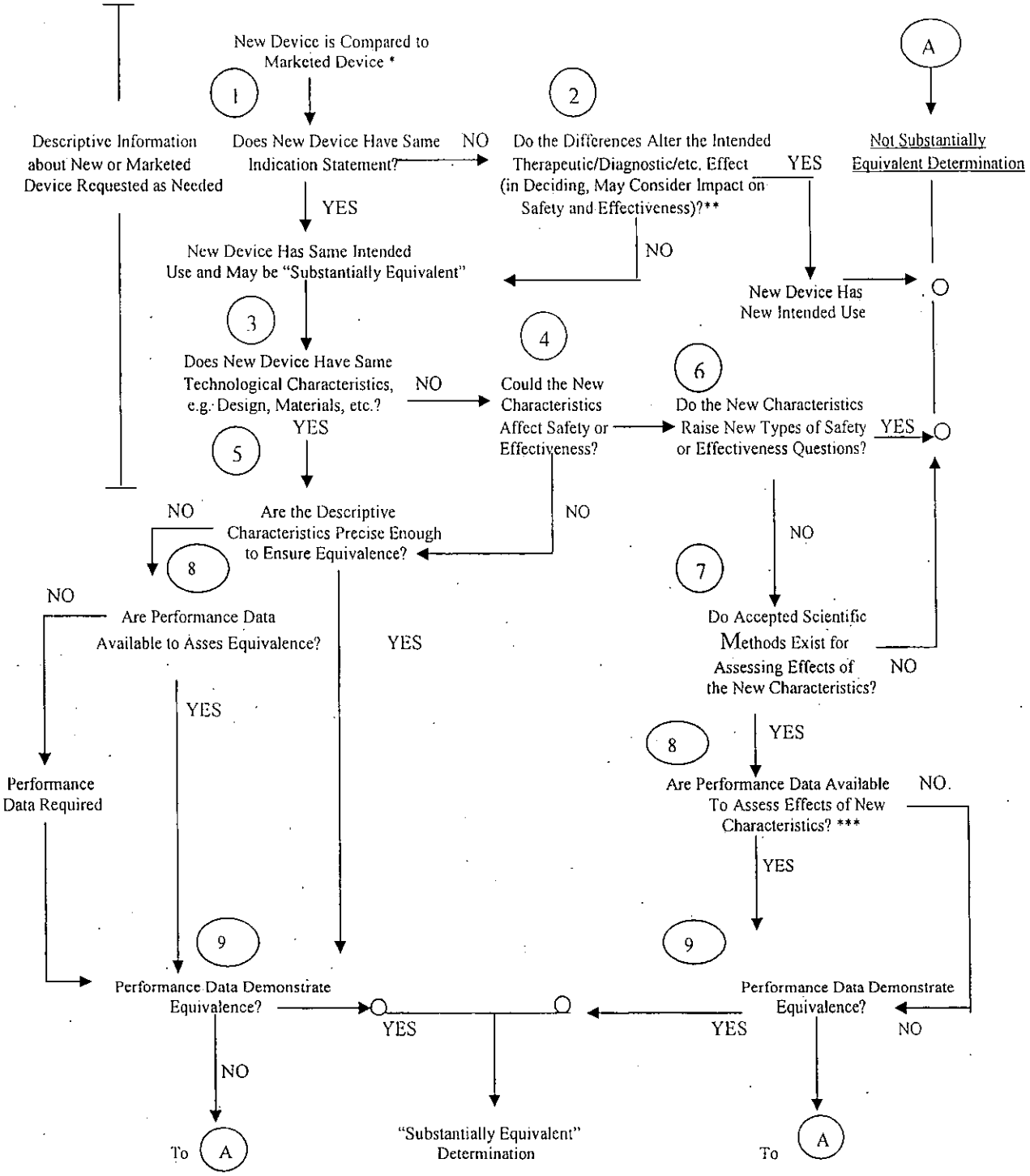
Review: BBP Linder (Branch Chief) OSDB (Branch Code) 6/1/11 (Date)

Final Review: (Division Director) (Date)

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

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



* 510(k) Submissions compare new devices 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 maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K110397/S001

Date: June 1, 2011
To: The Record
From: Christina Beardsley
Office: ODE
Division: DSORD/OJDB
510(k) Holder: DePuy Orthopaedics, Inc.
Device Name: DePuy TruMatch™ Patient Specific Instruments
Contact: Nancy Friddle, Project Manager, Regulatory Affairs
PO Box 988
700 Orthopaedic Drive
Warsaw IN 46581
Phone: (574) 371-4923
Fax: (574)371-4987
Email: nfriddle@its.jnj.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the DePuy TruMatch™ Patient Specific Instruments into interstate commerce. The proposed subject devices are patient-matched instruments indicated for use in the implantation of DePuy total knee arthroplasty devices (Sigma and Attune Knee Systems). Based on preoperative CT scans and preferences input by the surgeon, surgery is planned virtually by DePuy engineers and approved by the surgeon. The TruMatch guides are then created from the plan; some of the initial steps of the TKA implantation are performed with the sterile, disposable TruMatch pin guides or cutting guides, and the rest of the procedure is finished with traditional instrumentation.

The submission was initially placed on hold on February 18, 2011 because there was (b)(4) (b)(4) for a substantive review. Supplement 001 contained (b)(4) . However, as noted in the consulting review by Joseph Jorgens, III (OSEL/DESE), several (b)(4) . (This was previously communicated to the firm on April 26, 2011, and DePuy is working to collect this additional information). In addition, there is (b)(4) Therefore, I recommend that the submission be placed on telephone hold.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Prescription device)	X		
Truthful and Accuracy Statement *On page 00010 in the original submission*	X		
510(k) Summary *On page 00008 in the original submission*	X		
Standards Form		x	

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

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)? *The device is not an implant, but it is an accessory to an implant and expected to affect its safe and effective use.*		X	
Does the device design use software?	X		
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

The subject devices are sterile, single use instruments which are designed via information in preoperative imaging and intended to assist in positioning the distal femoral and proximal tibial cuts during total knee arthroplasty with DePuy implants (Sigma Fixed Bearing Implants and Attune Total Knee Implants). Trumatch™ Patient Specific Instruments are manufactured from RenShape® (b)(4) and stainless steel. They are marked with the patient name, patient date of birth, size and anatomy (right or left). There are two versions: cutting guides and pin guides. The cutting guides are like the pin guides, (b)(4) . After the initial pin placement (with the pin guides) or cutting (with the cutting guides) is performed with the TruMatch™ Patient Specific Instruments, standard instruments and trials are used to complete the knee implantation procedure.

As shown in Exhibit A, TruMatch (b) " have a variety of catalog numbers, depending on the size and (left or right) side of the implant they are being used with. They may be (b)(4) (b)(4) ,

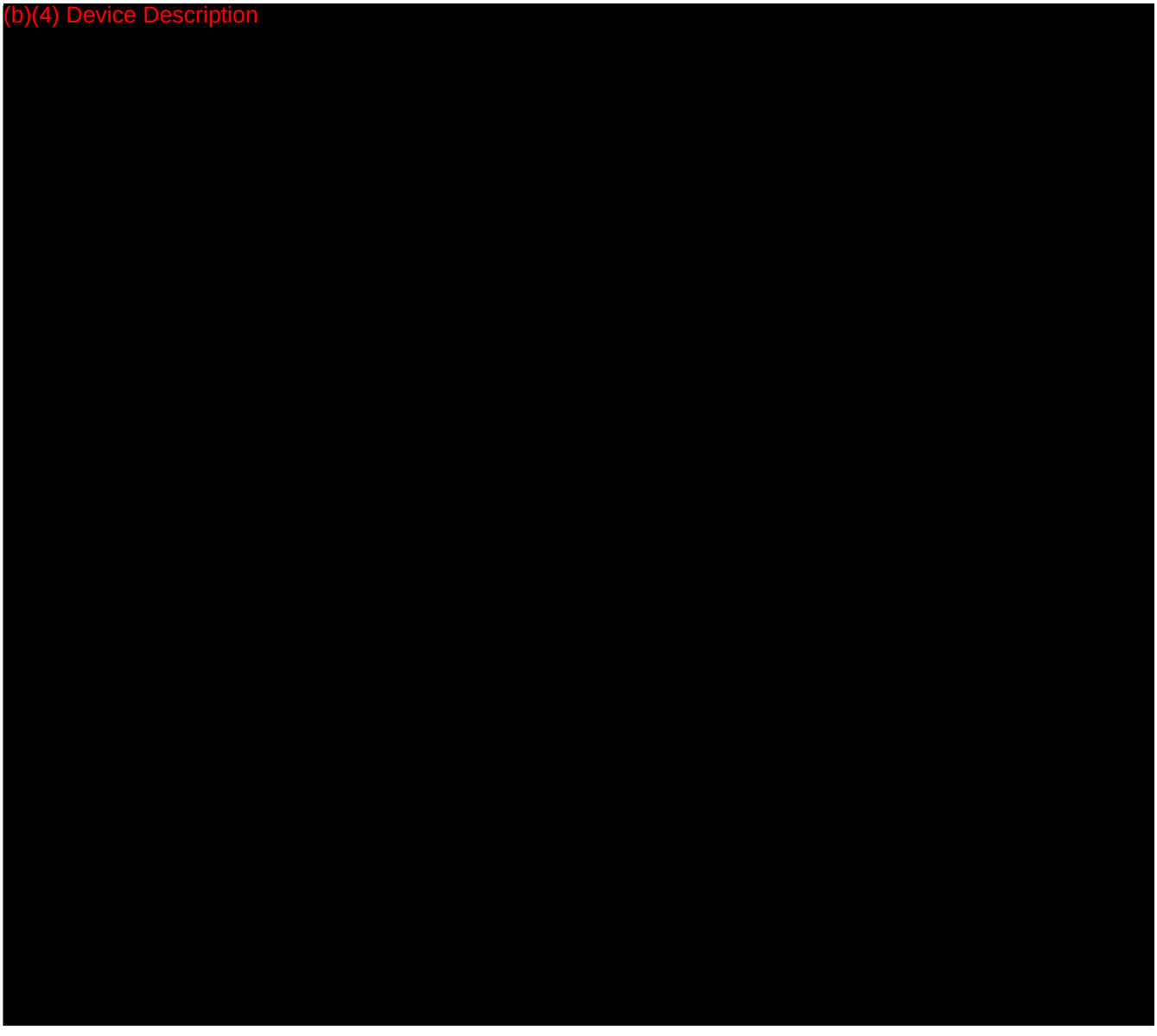
(b)(4)

Because the device design is patient-specific (differs from patient to patient), it is not possible for the sponsor to describe the geometry and sizing of the device. In lieu of this, the appropriate device description is a detailed description of the design algorithm that is invoked for each patient, which the company should demonstrate is reproducible (not operator dependent), not changing the surgical goal, and results in positioning and orientation of the TKA implant which is comparable to that achieved with the traditional (i.e., non-patient-specific) instruments. A summary of the process is below:

(b)(4)

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

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(b)(4) Device Description

(b)(4) Device Description

different

(b)(4) Deficiencies

(b)(4)

(b)(4) Device Description

(b)(4)

(b)(4) Deficiencies

(b)(4)
Device

(b)(4) Device Description

(b)(4) Deficiencies

(b)(4) Device Description

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(b)(4) Device Description

[redacted]

(b)(4) Deficiencies

[redacted]. *It appears that after the CT is "processed" the 3D model bone of the bone surfaces is*

64

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

(b)(4) Device Description (b)(4) Deficiencies

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65

(b)(4) Device Description

(b)(4) Deficiencies

(b)(4) Device Description

(b)(4) Device (b)

(b)(4) Deficiencies

(b)(4) Device Description

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

(b)(4) Device Description

[redacted]

(b)(4) Deficiencies

[redacted]

IV. Indications for Use

The Indications for use are as follows:

"The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intraoperatively and in guiding the marking of bone before cutting.

The TruMatch™ Patient Specific Instruments are intended for use with existing DePuy Orthopaedics, Inc. knee systems and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only."

(b)(4) Deficiencies

[redacted]

V. Predicate Device Comparison

The predicate devices that the sponsor identifies are the Smith & Nephew Patient Matched Cutting Blocks (K082358).

The Indications for use of the predicates are given below:

510(k) Number	Indications for use	Comments
K082358	Smith & Nephew's Patient Matched Cutting Blocks are intended to be used as patient-specific surgical instrumentation to assist	*This indication is similar. Smith & Nephew did not*

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	in the positioning of total knee replacement components intraoperatively and in guiding the marking of bone before cutting. The Patient Matched Cutting Blocks are intended for use with existing Smith & Nephew, Inc. knee systems and their cleared indications for use.	*list the specific knee systems that the guide is to be used with, but all subsequent systems have.* ***The sponsor should as well.***

(b)(4) Deficiencies [redacted]

The sponsor's submission provides an overview comparing the basic surgical procedure steps for using the subject device versus the Smith & Nephew predicate (Table 2, original submission, pages 00018-00021), and for using the subject device versus their own traditional instrumentation (Table 3, original submission, pages 00022-00025).

Conceptually, the basic device design of the Smith & Nephew Patient Matched Cutting Blocks is similar to the design of the subject device. Although intended for use with Smith & Nephew knee systems instead of DePuy knee systems, this predicate does use 3D preoperative imaging of a hip to ankle scan to model the patient's anatomy, locate landmarks, construct mechanical axes, and plan a TKA procedure, based on input surgeon preferences for the case; it uses similar software packages to the TruMatch device as well; and it ultimately yields an approved surgical plan from which a patient-specific cutting guide is manufactured.

The Smith & Nephew predicate guide is made from nylon (b)(4) *material, whereas the subject device is made from stainless steel and RenShape* (b)(4) *. To address this material difference from predicate devices, biocompatibility information is needed. This was supplied by DePuy. (See Section VIII of this memorandum for further details).*

VI. Labeling

The sponsor has included labeling materials in Exhibit C of the submission. This includes a draft package insert, a surgical technique, and draft package labels. Labeling includes an appropriate prescription use statement (in the form of a symbol on the package label) as required by CFR 21.801.109(b)(1).

The outer package label includes the manufacturer's name and address and telephone number (*since this is manufactured abroad, it lists all this information for both DePuy International and DePuy Orthopaedics, Inc. (the US company)*), the device name and device size and model (left/right), a graphic depiction of the device, the patient's name, the patient's date of birth, the surgeon's name, the knee system that it is intended for use with, the materials, the expiration date, catalog and batch numbers, and indicates that the device is sterilized by irradiation and single use. The package also indicates not to use the device if the package is damaged and to see the instructions for use. There are symbols on the label, but the same information is also conveyed in text on a separate package label (*this meets ODE requirements*).

The instructions for use in the package insert describe the device, stating that it is provided sterile and if the package is damaged, it should not be used, because it cannot be resterilized. It gives some information on patients who the device is intended for (those with osteoarthritis that meet the criteria for primary fixed and mobile bearing total knee replacement performed with a measured resection technique, who have mild bone deformities and/or angular deformities less than 15° of fixed varus/valgus or flexion, and do not have implants that cannot be kept away from the knee of interest). Instructions for use also include indications, contraindications (previous knee replacement of the same knee; *this is appropriate, as anatomy necessary to create the guide has been resected and/or may be obscured by metal artifact*), and cautions. The cautions include:

- Any metal device that will cause scatter in the CT throughout the knee
- Angular deformities greater than 15 degrees of fixed varus, valgus, flexion or tibial slope exceeding 15 degrees
- Moderate to severe bony deformities, Charcot knee, or patients with severe patella tendon calcifications that may prevent patella eversion

The surgical technique includes pictures and text description. It clearly illustrates all steps of the technique and how the subject device is used during the procedure. It also states that use of the TruMatch represents an addendum to the technique with uses the Sigma High Performance (HP) instruments, and that the surgeon must be familiar with the use of the Sigma HP instruments, as these are required in steps prior to, and following, the utilization of the TruMatch guides. Along with the guides, the surgeon is sent the Patient Proposal (i.e., the surgical plan) which shows views of the guide relative to the segmented patient anatomy, to help the surgeon position the guide correctly. On the tibial side, an alignment adapter and rod are used to help verify that the cut the guide would produce is appropriate. According to the technique, the guide should not have to be forced to seat properly, and when in its optimum position, it should not toggle or rock. The technique notes that if it is necessary to adjust ligament tension, the distal aspect of the femur or the proximal aspect of the tibia can be re-cut to achieve proper balance, using the regular HP instrument cutting/resection guides, which fit over the pins placed by the TruMatch instruments. (b)(4) Deficiencies [redacted]

The sponsor has included a 510(k) Summary. *This document does list all systems that the TruMatch instruments can be used with. It identifies predicate devices (though not by 510(k) number), and appears to meet the requirements of 21 CFR 807.92.* (b)(4) Deficiencies [redacted]

The indications for use in the 510(k) Summary and throughout the labeling matches the indications on the IFU form verbatim.

VII. Sterilization/Shelf Life/Reuse

TheTruMatch™ Patient Specific Instruments are sterilized using (b)(4) [redacted]. The (b)(4) [redacted]).

According to DePuy, the subject device is packaged in a rigid (b)(4) [redacted] tray and sealed with (b)(4) [redacted] lid. *These packaging materials are appropriate for a* (b)(4) [redacted] *device.* DePuy states that the packaging system for the TruMatch has been validated for an 11-year shelf life. (b)(4) [redacted] *The shelf life days on the sample label are listed as 120 days. This is more appropriate, but* (b)(4) [redacted]

The devices are not labeled as pyrogen free and the company has conducted pyrogen testing. *Based on OJDB historical practice, sponsors have not been required to submit pyrogenicity testing for review, even*

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for implant devices, unless they are making a pyrogen-free claim in the labeling.

VIII. Biocompatibility

In Exhibit D, DePuy provided (b)(4) tests on the (b)(4) Renshape (b)(4) material that was conducted by (b)(4). The test article for all tests was (b)(4) (b)(4), produced via (b)(4)

Test	Summary of methods/results
(b)(4)	

(b)(4) Testing

[redacted]

IX. Software

The sponsor explains that TruMatch™ Software consists of the TruMatch™ (b)(4) [redacted] (and the TruMatch™ Design Software. The TruMatch™ (b)(4) [redacted] is a web page that will be used by surgeons to securely configure surgical preferences, review patient proposals, request patient proposal modifications and approve patient proposals. The TruMatch™ Design Software is a compilation of OTS software tools ((b)(4) [redacted] that are used in-house by trained Design Operators to create TruMatch™ Patient Specific Instruments.

Joseph Jorgens, III (Senior Biomedical and Software Engineer, OSEL/DESE) provided a consulting review for the device software documentation, which was provided in S001. As discussed by Dr. Jorgens in his attached memorandum, there are outstanding issues related to the (b)(4) [redacted] These deficiencies were forwarded to Nancy Friddle via email on April 27, 2011; additional information to address these issues has not yet been provided.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XI. Performance Testing -- Bench

(b)(4) [redacted]

Testing submitted by DePuy is summarized below:

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

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XII. Performance Testing – Animal

No animal performance testing was provided in this submission.

XIII. Performance Testing – Clinical

No clinical testing was provided in this submission.

XIV. Substantial Equivalence Discussion

Evaluation of additional information, including elements of the device description, is required before a substantial equivalence discussion can be completed. At this time, based on available information, it does appear that the subject device has a similar intended use to other patient-matched instruments for total knee arthroplasty.

XV. Deficiencies

(b)(4) Deficiencies

[redacted]

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(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

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(b)(4) Deficiencies

[redacted]

XVI. Contact History

04-26-11 I phoned Ms. Friddle, in response to the voicemail she left on 4/21, requesting that I call. She wanted to know the status of the review and discussed the logistics of the PMA Supplement submission, for use of this device with DePuy's mobile bearing knee. I informed her that the file was still under review, but that the (b)(4) submitted in S001 was deficient.

04-27-11 I emailed Ms. Friddle (b)(4) deficiencies based on Dr. Jorgens' review and told her that I was not placing the submission on hold at this time.

05-12-11 Ms. Friddle emailed Dr. Jorgens (CCed to me at my request) to confirm a 1 pm teleconference related to some of the 04-27-11 deficiencies. There had been some earlier discussions between Ms. Friddle and I in which she confirmed, as I had indicated in the 04-27-11 email, that it was acceptable for

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DePuy to communicate directly with Dr. Jorgens on the (b)(4) .

05-13-11 Teleconference between DePuy (Nancy Friddle, Luke Aram, Jamie and John (software team)) and Joseph Jorgens III, in which I listened but did not actively participate. Items of discussion included the (b)(4) Deficiencies

XVII. Recommendation

Due to the deficiencies outlined above, I recommend that the submission be placed on telephone hold, with the items above communicated to the sponsor via email.

Christina Beardsley, PhD Reviewer — Date 6/1/11

Acting Branch Chief — Date 6/1/11

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

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Beardsley, Christina

From: Beardsley, Christina
Sent: Wednesday, June 01, 2011 3:46 PM
To: 'Friddle, Nancy [DPYUS]'
Subject: K110397

Dear Ms. Friddle,
In order to complete my recommendation on your submission for the TruMatch™ Patient Specific Instruments, I need additional information to address each of the following:

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

(b)(4) Deficiencies

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MEMO OF

SOFTWARE REVIEW

of a MODERATE Level Of Concern device

510(k): K110397/S001

DATE: 4/19/11

FROM:	Joseph Jorgens III, Senior Biomedical and Software Engineer		OSEL-DESE	301-796-2588
TO:	Christina Beardsley	ODE/DSORD/OJDB	Bldg 66 1506	301-796-6404

SUBJECT: Software review of DePuy Orthopedics's TruMatch Patient Specific Instruments. 700 Orthopaedic Drive, Warsaw, Indiana. Contact: Nancy Friddle, Project Manager, Regulatory Affairs: 574-371-4923.

Succinct Conclusion: ADDITIONAL INFORMATION REQUIRED

The information provided in this submission is insufficient to meet the software concerns as described in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, and it is recommended that, from a software standpoint, additional information be acquired in order to complete the review of this submission.

SUMMARY:

The TruMatch Patient Specific Instruments are single-use devices that are preoperatively designed to assist in the positioning of a joint replacement component intra-operatively and in guiding the distal femoral and proximal tibial cuts for a particular patient. A TruMatch Patient Specific Instrument set includes a proximal tibial and distal femoral device. (b)(4) [redacted].

(b)(4) [redacted]

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

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(b)(4)

[redacted]

The TruMatch process has 13 steps:

Step	Description	Who does it
1.	Register for TruMatch	Surgeon and DePuy
2.	Prescribe CT scan for patient	Surgeon
3.	Receive CT scan and verify scan parameters	DePuy
4.	Complete patient registration	Surgeon
5.	Process CT scan	DePuy
6.	Create surgical plan	DePuy
7.	Create patient proposal document	DePuy
8.	Review patient proposal document, request changes, as needed, and approve	Surgeon
9.	Update surgical plan and patient proposal per surgeon request	DePuy
10.	Update TruMatch instrumentation design per the approved surgical plan	
11.	Inspect all design documentation	DePuy
12.	Manufacture, package and inspect TruMatch instrumentation	DePuy
13.	Sterilize TruMatch instrumentation	DePuy Supplier

1. Registering for TruMatch involves three steps.

a. The surgeon must complete the registration form and list his or her surgical preferences. Surgeon preferences are the surgical options provided by TruMatch. They are the same options that are provided by manual instruments and include Femoral Resection Level, Femoral Resection Reference, Femoral Rotation Angle, Femoral Rotation Reference, Femoral Sizing Preference, Tibial Resection Level, Tibial Resection Reference, and Tibial Slope.

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b. The surgeon or imaging center must submit a test CT scan of an anatomic model (plastic bone) that meets the requirements outlined and on file at DePuy. Once the CT scan and surgeon preferences are verified by DePuy, a surgeon is registered and can begin the TruMatch process.

c. After DePuy has verified steps a. and b. above, the surgeon is provided with a unique user name and password for access to the Teamcenter Surgeon interface.

2. A CT scan prescription is completed by the surgeon before the patient is scanned.

3. The CT scan is then received by DePuy and it is inspected for correct patient ID and protocol parameters using a DePuy checklist. If everything is correct, the surgeon is notified to complete the patient registration.

4. The surgeon then completes patient registration via the Teamcenter Surgeon interface. The surgeon enters the case information such as patient alignment (varusor valgus), patient height, patient weight, patient joint space loss, and instrument preference (cutting guide or pin guide). The surgeon also confirms correctness of patient name and anatomy (left or right). The surgeon has control to edit any of the surgical preferences at this point.

5. Next, DePuy processes the CT scan. The distal femur, proximal tibia, and proximal fibula are segmented from the scan and converted into (b)(4). Additionally, surgical landmarks are identified by DePuy that are used in the surgical planning step. Landmarks that are selected by DePuy design engineers include the (b)(4).

6. DePuy creates a surgical plan using (b)(4). If needed, the DePuy engineer will make (b)(4).

7. DePuy creates a patient proposal document that illustrates the surgical plan and can be reviewed by the surgeon. The patient proposal is a PDF document that is generated from (b)(4). The PDF document cannot be edited by the surgeon. It contains a summary of surgeon preferences and requests (b)(4). The patient proposal includes (b)(4). The patient proposal also includes the above mentioned landmarks and (b)(4). Additional measurements include the (b)(4) (b)(4).

8. The surgeon reviews the patient proposal document on the TruMatch Teamcenter Surgeon interface. The surgeon must make requested changes through the TruMatch Teamcenter Surgeon interface as he or she cannot edit the PDF patient proposal document or the NX CAD file. The TruMatchTeamcenter Surgeon interface gives the surgeon four options when reviewing a patient proposal: 1) approve as is, 2) approve with changes, 3) redesign and resubmit, and 4) cancel case.

If the approve with changes or redesign and resubmit option is selected, the surgeon must type in changes or select changes from a pre-defined list. If the redesign and resubmit option is selected, the changes are made and then the surgeon must approve the changes in the PDF patient proposal document before manufacturing begins. Upon surgeon approval, the surgeon's personal password must be entered into the Teamcenter software. Common changes include updates in resection level, femoral implant rotation, tibial slope, and implant size. The TruMatch Teamcenter Surgeon interface allows the surgeon full control of the surgical planning process while prohibiting them from directly editing the design files.

9. If changes are requested, the surgical plan and patient proposal document is then updated by DePuy.

10. DePuy then updates TruMatch device design per the approved surgical plan and patient specific bone models. The shape of the patient's (b)(4) the TruMatch device. (b)(4)

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

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(b)(4)

11. A(b) (

12. Using the approved CAD model, TruMatch device is manufactured and inspected.

13. Each TruMatch device is packaged and sterilized by (b)(4).

Software Controlled Aspects of the Device

All components of the device are controlled/monitored by (b)(4) (b)(4).

SOFTWARE REVIEW

1. **Level of Concern: Acceptable**
In the Supplement, in Section 1 entitled Level of Concern, the firm provided the correct determination of the Level Of Concern and included their supporting rationale: MODERATE.

2. **Software Description: Acceptable**
In the original submission beginning in the Section entitled Device Description and in S001 in Exhibit D entitled System Architectural Design Document, the firm provided an acceptable overview of the device features that are controlled by software, and a description of the intended operational environment, which includes information on the programming language, the hardware platform and the operating system.

(b)(4) Deficiencies

4. **Software Requirements Specifications (SRS): Acceptable**
In the Supplement, in the Section entitled Software Requirements, the firm provided an acceptable copy of the Software Requirements Specification document, which documented the (b)(4), (b)(4).

5. **Architecture Design Chart: Acceptable**
In the Supplement, in the document entitled Software Architecture, the firm provided an acceptable detailed depiction of (b)(4).

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

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6. (b)(4) Deficiencies

7. (b)(4) Deficiencies

8.

9.

10. **Revision Level History: Acceptable**
In the Supplement, in Appendix C, entitled Software Release Level, the firm provided an acceptable revision history log, which provides the history of software revisions generated during the course of product development.

11. (b)(4) Deficiencies

12.

RECOMMENDATION: ADDITIONAL INFORMATION REQUIRED

For the reasons specified supra, it is recommended that the firm should be asked for the following additional information before final approval is considered.

I will be happy to discuss these matters with the firm directly if that is more desirable. The following verbiage is offered as a possibility for inclusion in any oral or written correspondence with the firm.

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

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If you have questions concerning these additional information requests, please contact Joseph Jorgens III on 301-796-2588.

Prior to submitting the additional information, please familiarize yourself with the following software guidance documents:

"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf) 5/11/05

"Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf) (issued 9/9/1999)

"General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (issued 1/11/2002) (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085371.pdf)

"Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software". (issued 1/14/05) (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf)

You may also want to consider a review of the following consensus standards: IEC 62304:2006 (Medical device software – Software life-cycle processes) and ISO 14971:2000 (Medical devices - Application of risk management to medical devices).

For all the following information, please provide a table of contents with page numbers and tabbed sections, with each section repeating the question which is being addressed and clearly providing the answers to each of these additional information questions. If some of the information was provided in the original submission, please repeat that information in your response: do not just reference some previously submitted information.

(b)(4) Deficiencies

[redacted]

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

(b)(4) Deficiencies

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(b)(4) Deficiencies

[redacted]

Please provide information, as appropriate, on the Cybersecurity aspects of your device, including, but not limited to, the following facets of information security with respect to communications features of your device and associated software: Confidentiality, integrity, availability and accountability.

Confidentiality assures that no unauthorized users have access to the information.

Integrity is the assurance that the information is correct - that is, it has not been improperly modified.

Availability suggests that the information will be available when needed.

Accountability is the application of identification and authentication to assure that the prescribed access process is being done by an authorized user.

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

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

COVER SHEET MEMORANDUM

From: Reviewer Name Christina Beardsley

Subject: 510(k) Number K110397

To: The Record

Please list CTS decision code TH

☐ 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)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
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)			
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			
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)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
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.)			

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

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Transitional Adolescent B (18 -<= 21, No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/168.html) *Contact OC.*

Regulation Number	Class*	Product Code

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

Additional Product Codes: _____

Review: _____ 5508 2/24/2011
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 2/24/2011
for (Division Director) (Date)

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

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Beardsley, Christina

From: Beardsley, Christina
Sent: Wednesday, February 23, 2011 7:45 PM
To: 'Friddle, Nancy [DPYUS]'
Cc: 'jjohns70@its.jnj.com'
Subject: RE: K110397

Dear Nancy,
Thank you for providing an estimate of the time it will take to collect the (b)(4) for the Trumatch. Per our discussion today, I am placing your submission on telephone hold at this time.
Kind regards,
Christina

From: Beardsley, Christina
Sent: Friday, February 18, 2011 3:31 PM
To: 'Friddle, Nancy [DPYUS]'
Subject: K110397

Dear Ms. Friddle,
I am reviewing your submission for the TruMatch™ Patient Specific Instruments. While I have not yet had the opportunity to conduct a substantive review of other aspects of the submission, I note that your process for creating the patient-matched guides includes software (b)(4) . This information will be needed to complete a review of this file.

Prior to submitting the additional information, please familiarize yourself with the following software guidance documents:

- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf, issued 5/11/05)
- "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf, issued 9/9/99)
- "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085371.pdf, issued 1/11/02)
- "Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf, issued 1/14/05)

Please ensure that your recommended Operating Systems and browsers are those that you have tested.

(b)(4) Deficiencies

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

(b)(4) Deficiencies

[redacted]

Through CDRH Learn, there is also a module available (fourth item down on the course list) on the topic of software, which you may find useful, that some firms have considered an informative aid in determining software requirements for premarket submissions and for Quality System Regulation compliance:
http://www.fda.gov/Training/CDRHLearn/ucm162015.htm

I am uncertain whether or not DePuy has this information readily available and can provide it within a few business days, or if it will take some time to compile this information for submission. Please respond to this email to let me know whether or not you anticipate responding with all of the information by next Wednesday. If you would like additional time, I can place the submission on hold.

Kind regards,
Christina

Christina L. Beardsley, PhD
Biomedical Engineer

OJDB/DSORD/ODE/CDRH/FDA
WO66, Room 1506

99
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
email: christina.beardsley@fda.hhs.gov
ph: 301-796-6404

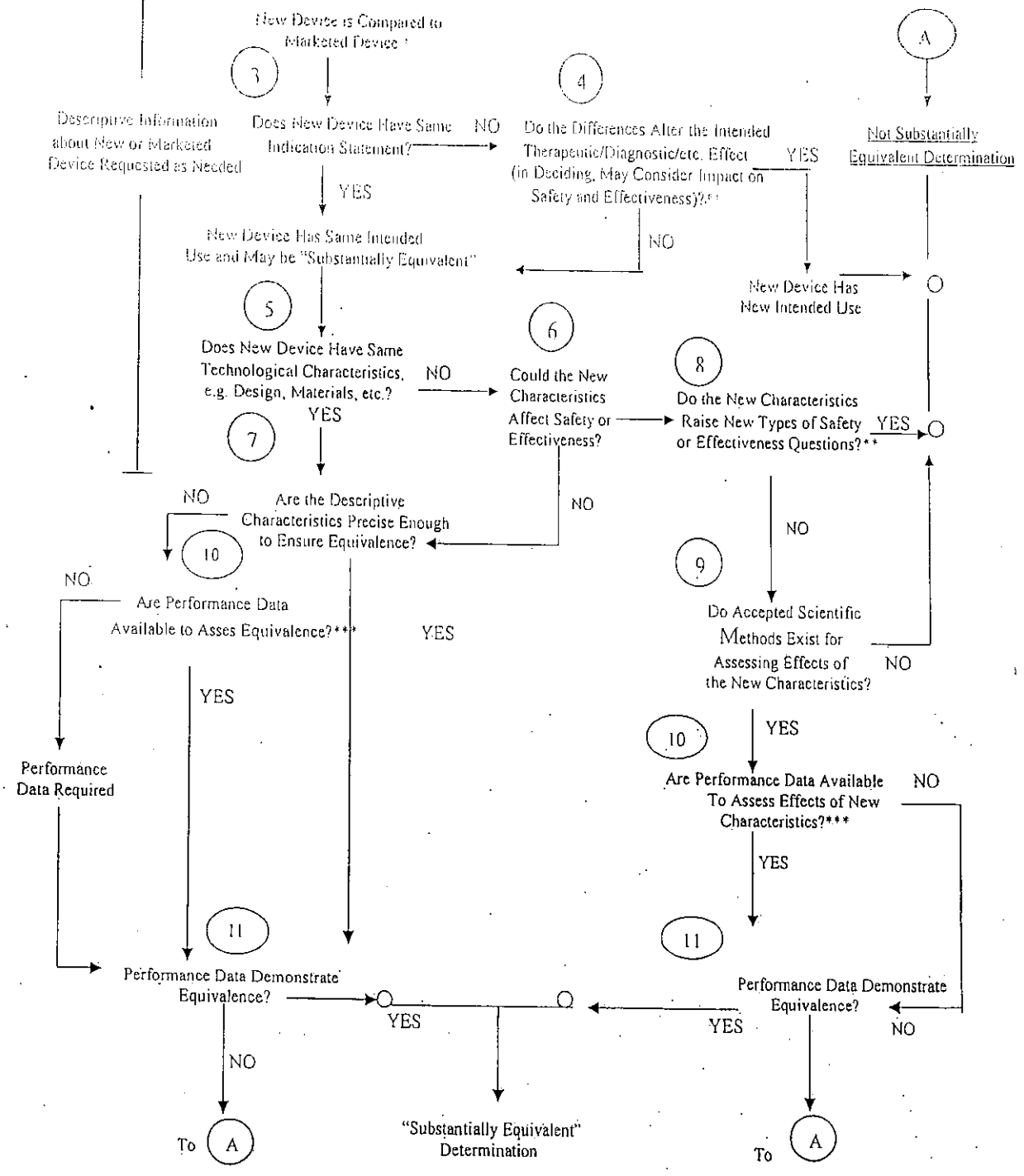
This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the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

100

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

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



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

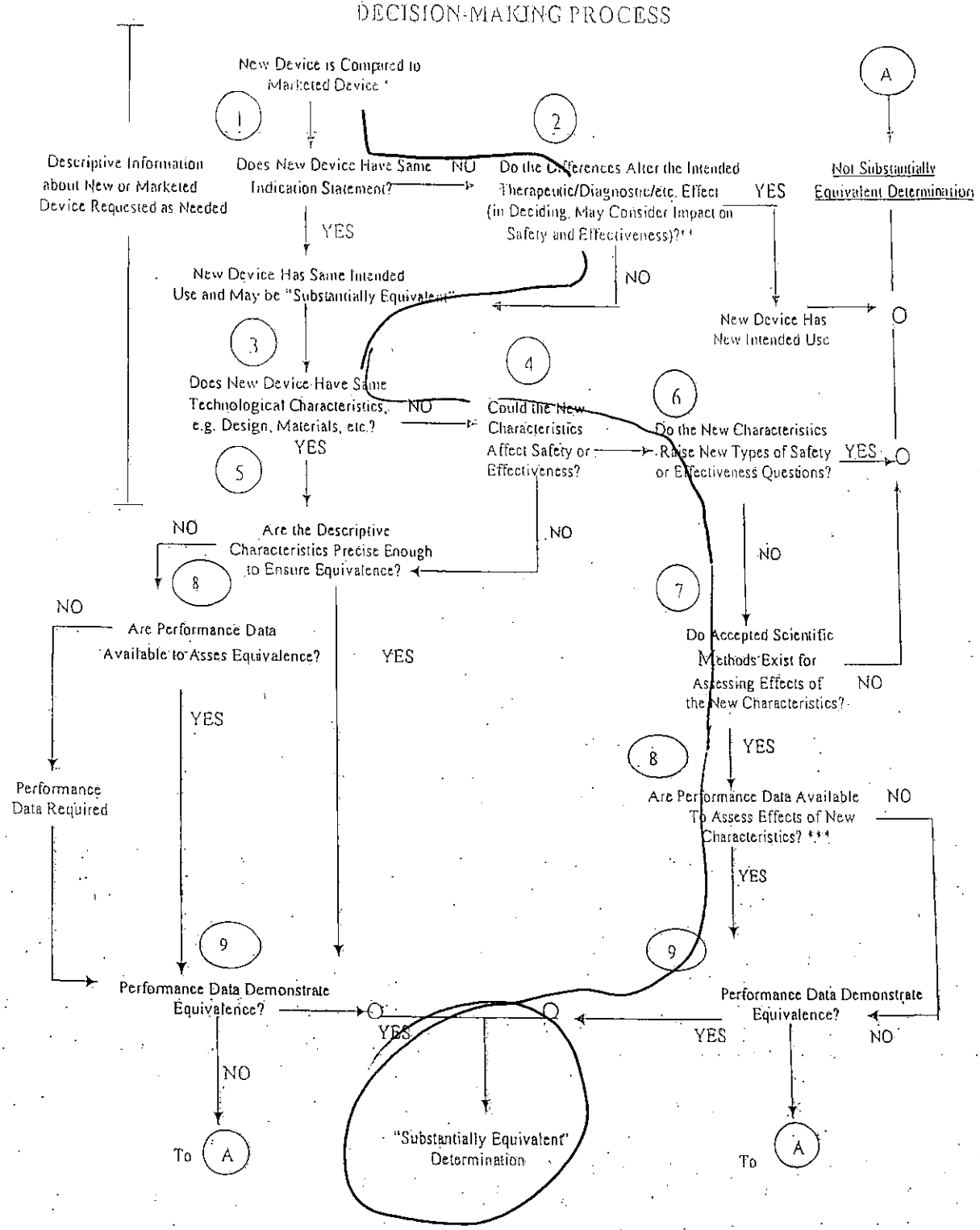
❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

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



* 510(k) Submissions compare new devices 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 maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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K110397/S1
DSORD/DRJ

DePuy Orthopaedics Inc.
a Johnson & Johnson company
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MAR 2 4 2011

Received K24 K25

March 23, 2011

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

Re: K110397, TruMatch™ Patient Specific Instruments-Responses to 2/23/11 email Deficiencies

Dear Dr. Beardsley:

DePuy Orthopaedics, Inc. is submitting responses to the February 23, 2011 email questions in duplicate (one paper and one CD). DePuy certifies that the .pdf file provided on the CD is an exact duplicate of the paper copy of these responses.

Pursuant to 21 CFR 807.95(c)(3), DePuy considers this 510(k) response to be confidential commercial information and requests that FDA treats it as such. DePuy has taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331 (q).

Thank you in advance for your prompt review of these responses. Please contact me by phone at (574) 371-4923, by email at nfriddle@its.jnj.com, or by FAX at (574) 371-4987 if you have further questions or need clarification on anything. Alternatively, you may contact Janet Johnson at (574) 372-7469 or by email at Jjohns70@its.jnj.com.

Sincerely,

Nancy Friddle

Nancy Friddle
Project Manager, Regulatory Affairs

PO Box 988, 700 Orthopaedic Drive, Warsaw, IN 46581-0988
Phone 574-267-8143 Fax 574-371-4865

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

DePuy Orthopaedics Inc.
a Johnson & Johnson company
never stop moving™

March 23, 2011

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

Re: K110397, TruMatch™ Patient Specific Instruments-Responses to 2/23/11 email Deficiencies

Dear Dr. Beardsley:

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Thank you in advance for your prompt review of these responses. Please contact me by phone at (574) 371-4923, by email at nfriddle@its.jnj.com, or by FAX at (574) 371-4987 if you have further questions or need clarification on anything. Alternatively, you may contact Janet Johnson at (574) 372-7469 or by email at Jjohns70@its.jnj.com.

Sincerely,

Nancy Friddle

Nancy Friddle
Project Manager, Regulatory Affairs

PO Box 988, 700 Orthopaedic Drive, Warsaw, IN 46581-0988
Phone 574-267-8143 Fax 574-371-4865

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

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

March 23, 2011

Dear Ms. Beardsley,

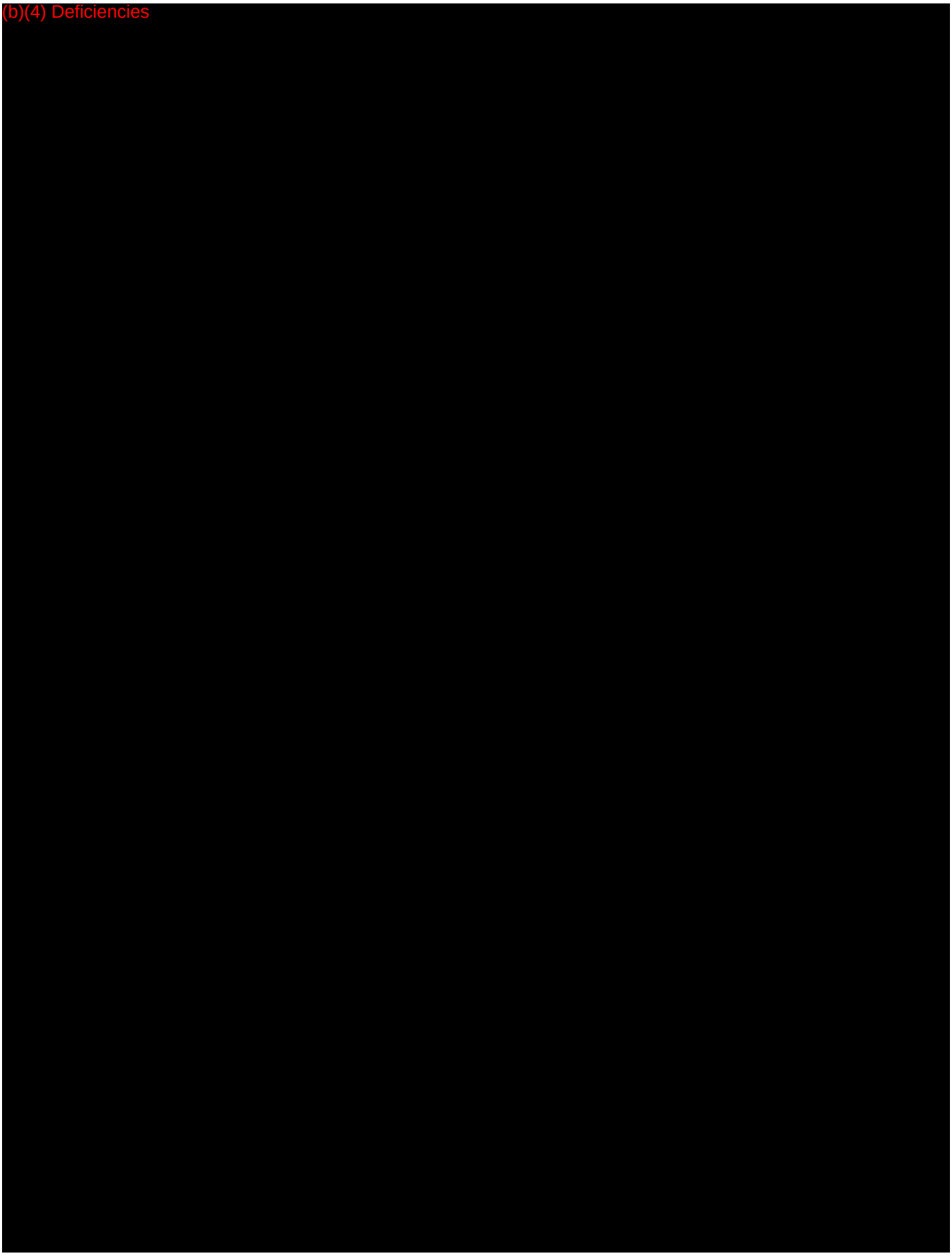
Listed below are DePuy's answers to your request for additional information for the submission for the TruMatch™ Patient Specific Instruments (K110397).

(b)(4) Deficiencies

[redacted]

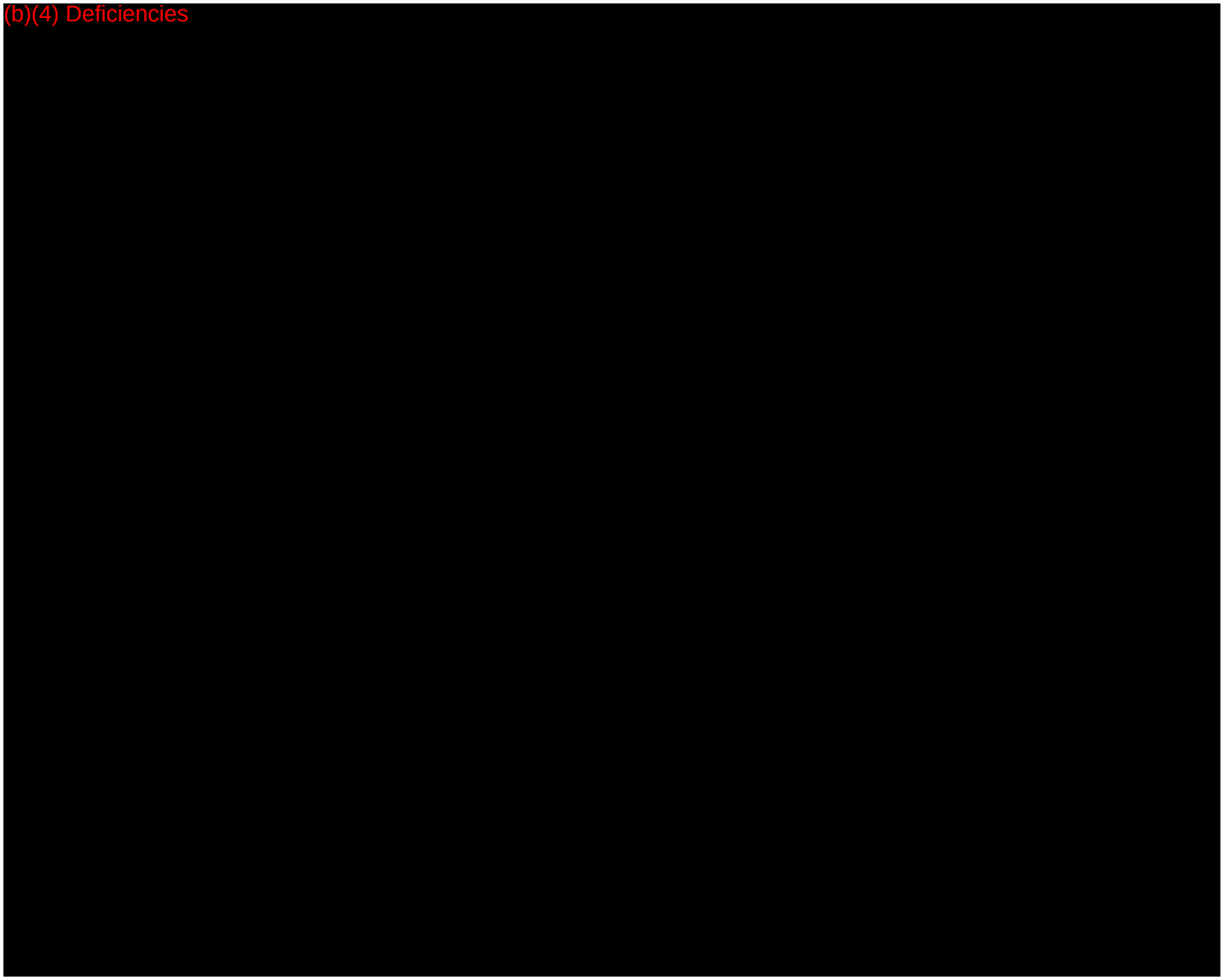
Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4) Deficiencies



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

(b)(4) Deficiencies



Please do not hesitate to contact us with any further questions or clarifications.

Kind Regards,

Nancy Friddle

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Software Verification Protocol
DePuy Orthopaedics Inc.
TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6)	03/15/2011
REVIEWED BY:		03/17/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011

Prepared by:
(b)(4)

Prepared for
DePuy Orthopaedics Inc.

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

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Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Verification Report
DePuy Orthopaedics Inc.
TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6) [redacted]	03/19/2011
REVIEWED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011

Prepared by:
(b)(4) [redacted]

Prepared for
DePuy Orthopaedics Inc.

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

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Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Software Verification Protocol DePuy Orthopaedics Inc. TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6)	03/15/2011
REVIEWED BY:		03/17/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/18/2011

Prepared by:
(b)(4)

Prepared for
DePuy Orthopaedics Inc.

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Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Software Hazard Analysis
DePuy Orthopaedics Inc.
TruMatch™

	NAME	DATE
PREPARED BY:	(b)(6)	3/5/2011
APPROVED BY:		3/19/2011
APPROVED BY:		3/20/2011
APPROVED BY:		3/19/2011
APPROVED BY:		3/20/2011
APPROVED BY:		3/20/2011
APPROVED BY:		3/20/2011
APPROVED BY:		3/20/2011

Prepared by:
(b)(4)

Prepared for:
DePuy Orthopaedics Inc.

DePuy Orthopaedics, Inc.
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Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Software Hazard Analysis

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Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Eff. Date: 03/21/2011		

System Architectural Design

DePuy Orthopaedics Inc.
TruMatch™ System

	NAME	DATE
PREPARED BY:	(b)(6)	03/15/2011
APPROVED BY:		3/19/2011
APPROVED BY:		3/20/2011
APPROVED BY:		3/19/2011
APPROVED BY:		3/20/2011
APPROVED BY:		3/20/2011
APPROVED BY:		3/20/2011
APPROVED BY:		3/20/2011

Prepared by:
(b)(4)

Prepared for
DePuy Orthopaedics, Inc.

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(b)(4) System Architectural Design

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Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Eff. Date: 03/20/2011		

Software Requirement Specification
DePuy Orthopaedics
TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6)	03/14/2011
REVIEWED BY:		03/14/2011
APPROVED BY:		3/17/2011
APPROVED BY:		3/17/2011
APPROVED BY:		3/17/2011
APPROVED BY:		3/17/2011
APPROVED BY:		3/17/2011
APPROVED BY:		3/17/2011

Prepared by:
(b)(4)

Prepared for
DePuy Orthopaedics

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

(b)(4) Software Reuirement Specification

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(b)(4) Software Reuirement Specification

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

DePuy Orthopaedics Inc.
TruMatch™ Software
Off the Shelf Analysis

	NAME	DATE
PREPARED BY:	(b)(6)	3/4/2011
REVIEWED BY:		3/8/2011
REVIEWED BY:		3/18/2011
APPROVED BY:		3/18/2011
APPROVED BY:		3/19/2011
APPROVED BY:		3/18/2011
APPROVED BY:		3/18/2011
APPROVED BY:		3/18/2011
APPROVED BY:		3/18/2011

Prepared by:
(b)(4)

Prepared for:
DePuy Orthopaedics Inc.

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

(b)(4) Off the Shelf Analysis

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(b)(4) Off the Shelf Analysis

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Eff. Date: 03/20/2011		

Software Design Description

TruMatch™ TeamCenter Surgeon Interface

	NAME	DATE
PREPARED BY:	(b)(6)	03/10/2011
REVIEWED BY:		03/18/2011
APPROVED BY:		03/18/2011
APPROVED BY:		03/19/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011

Prepared by:
(b)(4)

Prepared for:
DePuy Orthopaedics Inc.

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Questions? Contact FDA/CDRH/OCE/DID at 000278FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Software Design Description

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(b)(4) Software Design Description

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Test Traceability Analysis
DePuy Orthopaedics Inc.
TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6)	03/18/2011
REVIEWED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011
APPROVED BY:		03/20/2011

Prepared by:
(b)(4)

Prepared for
DePuy Orthopaedics

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(b)(4) Test Traceability Analysis

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Verification Plan
DePuy Orthopaedics Inc.
TruMatch™ Software

PREPARED BY:	(b)(6)	03/07/2011
REVIEWED BY:		03/14/2011
REVIEWED BY:		03/14/2011
APPROVED BY:		03/14/2011
APPROVED BY:		03/14/2011
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APPROVED BY:		03/14/2011
APPROVED BY:		03/14/2011
APPROVED BY:		03/14/2011

Prepared by:
(b)(4)

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Eff. Date: 03/21/2011		

Code Review Report
DePuy Orthopaedics, Inc.
TruMatch™ TeamCenter Surgeon Interface

	NAME	DATE
PREPARED BY:	(b)(6)	03/09/2011
REVIEWED BY:		03/20/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011

Prepared by:
(b)(4)

Prepared for
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(b)(4) Code Review Report

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Software Build Document

TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6)	03/10/2011
REVIEWED BY:		03/17/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011

Prepared by:
(b)(4)

Prepared for:
DePuy Orthopaedics Inc.

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Eff. Date: 03/22/2011		

Verification Summary Report
DePuy Orthopaedics, Inc.
TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6)	03/21/2011
APPROVED BY:		03/22/2011
APPROVED BY:		03/22/2011
APPROVED BY:		03/22/2011
APPROVED BY:		03/22/2011
APPROVED BY:		03/22/2011
APPROVED BY:		03/22/2011

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K110397/S7
OR/DSORD

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FDA CDRH DMC
JUN 16 2011
Received
Received K35

June 15, 2011

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

Re: K110397, TruMatch™ Patient Specific Instruments – Responses to questions contained in June 1, 2011 email

Dear Dr. Beardsley,

DePuy Orthopaedics, Inc. is submitting responses to the request for additional information sent via email on June 1, 2011 for the above-referenced TruMatch™ Patient Specific Instruments (K110397). This submission is being sent in duplicate (one paper and one exact duplicate CD). DePuy certifies that the .pdf file provided on the accompanying CD is an exact duplicate of the paper copy of these responses. Please note that this additional information is in response to questions one through eight of the June 1 email. The additional seven questions relating to (b)(4) contained in the June 1 email were previously responded to in a submission dated June 3 and received by FDA on June 6, 2011. **Both the submission dated June 3 and today's submission dated June 15, 2011 are "Add to File" responses to Supplement 1 to K110397 per a conversation with Christina Beardsley**.

To facilitate review, a table of contents with page numbers and tabbed sections has been provided. Each section repeats the question which is being addressed and clearly provides the answers to each of these additional information questions.

Pursuant to 21 CFR 807.9 (c) (3), DePuy considers this 510(k) response to be confidential commercial information and requests that FDA treats it as such. DePuy has taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your prompt review of these responses. Please contact me by phone at (574) 371-4923, by email at nfriddle@its.jnj.com, or by FAX at (574) 371-4987 if you have further questions or need clarification on anything contained in these responses. Alternatively, you may contact Janet Johnson at (574) 372-7469 or by email at Jjohns70@its.jnj.com.

Respectfully submitted,

Nancy Friddle

Nancy Friddle

PO Box 988, 700 Orthopaedic Drive, Warsaw, IN 46581-0988
Phone 574-267-8143 Fax 574-371-4865

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

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June 15, 2011

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

Re: K110397, TruMatch™ Patient Specific Instruments – Responses to questions contained in June 1, 2011 email

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Respectfully submitted,

Nancy Friddle

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PO Box 988, 700 Orthopaedic Drive, Warsaw, IN 46581-0988
Phone 574-267-8143 Fax 574-371-4865

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SECTION 1

(b)(4) Deficiencies

[redacted]

Answer #1a:

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

(b)(4) Deficiencies

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2. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: DePuy TruMatch™ Patient Specific Instruments

Indications for Use:

The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The anatomical landmarks necessary for the creation of the TruMatch™ Patient Specific Instruments must be present and identifiable on CT.

The TruMatch™ Patient Specific Instruments are intended for use with Sigma® Total Knee Implants and Attune™ Total Knee Implants and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

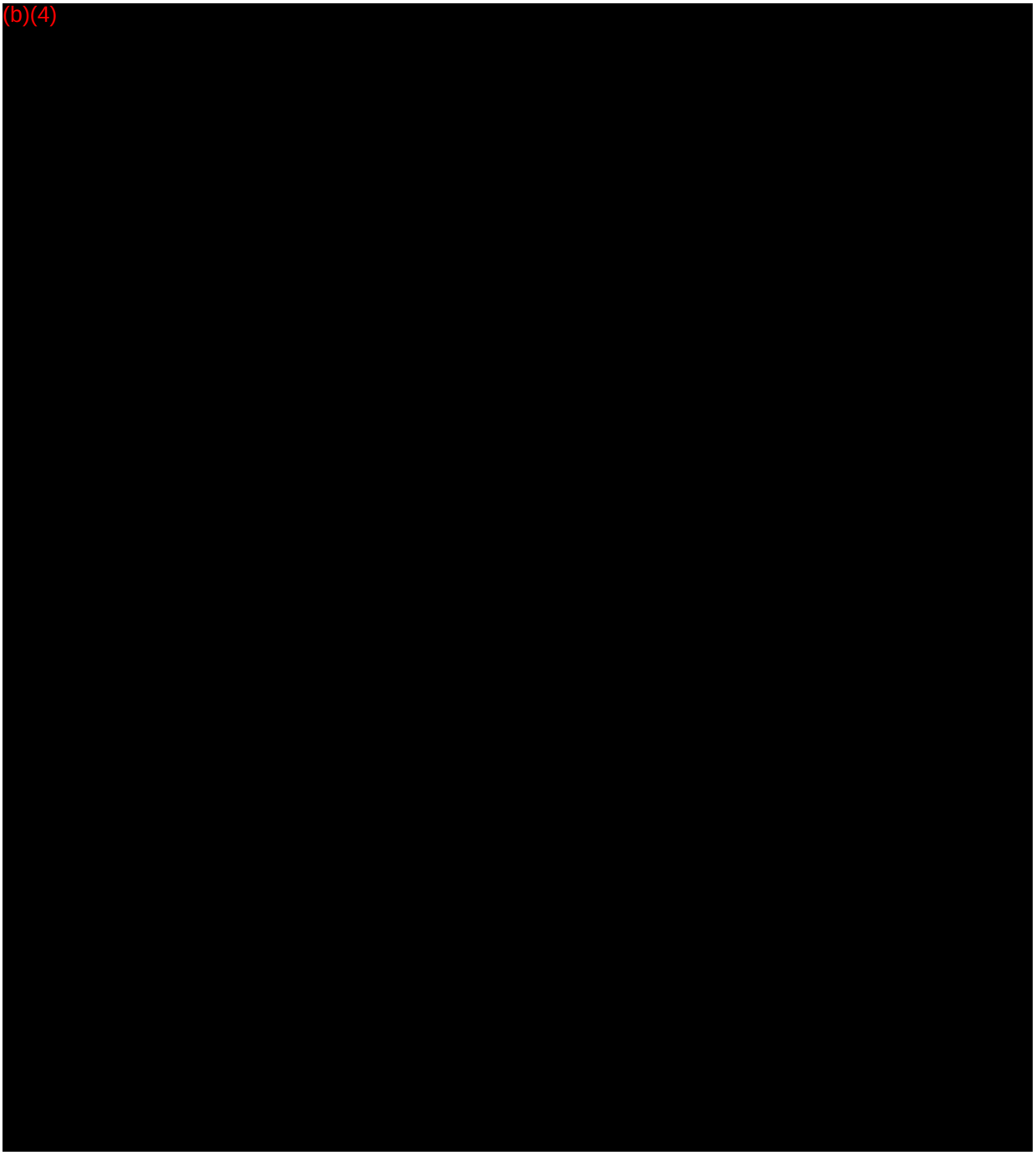
Concurrence of CDRH, Office of Device Evaluation (ODE)

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Exhibit B

Checklists for the Preoperative CT Scan and Segmentation

(b)(4)



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TruMatch™
PERSONALIZED SOLUTIONS

CT CENTER USER GUIDE

DePuy Orthopaedics, Inc. | 715 Orthopaedic Drive | Warsaw, Indiana 46582 | T: (800) 689-0746

TruMatch™ Knee Scanning Protocol

This protocol will allow DePuy Orthopaedics to accurately create a 3D model of the patient's bone and use it to design a patient specific knee instrument. Scan settings should be optimized to capture bony geometry of the affected knee. Hip and ankle data is needed to align the entire leg for a total knee replacement. Review the following information before proceeding with the scanning process.

Scanning Procedure Checklist

Use this checklist as a guide to make sure the important scan parameters are correct.

- ☐ Thick 5 mm spacing in hip and ankle
- ☐ Thin 0.5 to 0.8 mm spacing in knee
- ☐ Thick and thin slices do not overlap
- ☐ FOV is less than 20 cm
- ☐ Recon filter is correct (see page 2)
- ☐ If metal is present in contralateral knee, it is flexed away from joint line (see Figure 2)
- ☐ No metal present within 8 cm of joint (see Figure 1)
- ☐ Femoral head and talus are included
- ☐ No patient movement during scan
- ☐ DICOM header contains the following:
  - ☐ Patient Name
  - ☐ Patient Date of Birth
  - ☐ Patient Sex
  - ☐ Referring Physician (Name of Orthopaedic Surgeon)
  - ☐ Institution Name (Name of your CT Imaging Center)
  - ☐ Side Affected (Left or Right)

If the scan is run in separate studies or slabs:

- ☐ FOV is consistent for each slab
- ☐ Center point is consistent for each slab

Scanning Procedure

- All data must be collected with the same FOV and center (x/y) points.
- There should be no gaps and minimal overlap between the thick and thin slices.
- Patient movement during the scan will disqualify the study and require rescan.
- Minimize FOV with a maximum of 20 cm so the image captures one image above the femoral head and ends with one slice below the talus.
- Cropping off soft tissue to achieve a FOV of 20 cm is acceptable. Only images of bone are required.
- If there are metal devices in the contralateral knee, please see page 2 for instructions.
- Send only axial images in uncompressed DICOM format.

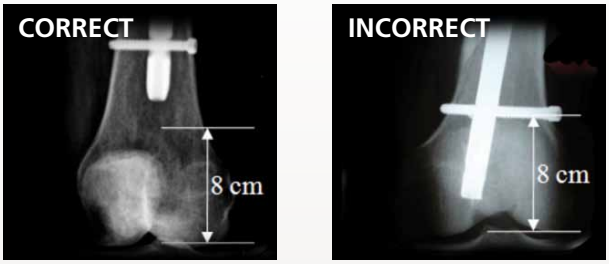


Figure 1

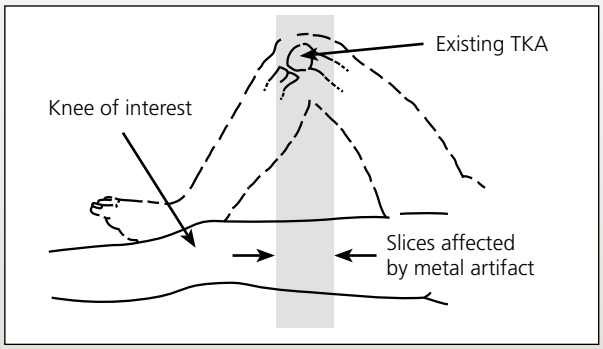


Figure 2

Please save this document for reference.

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

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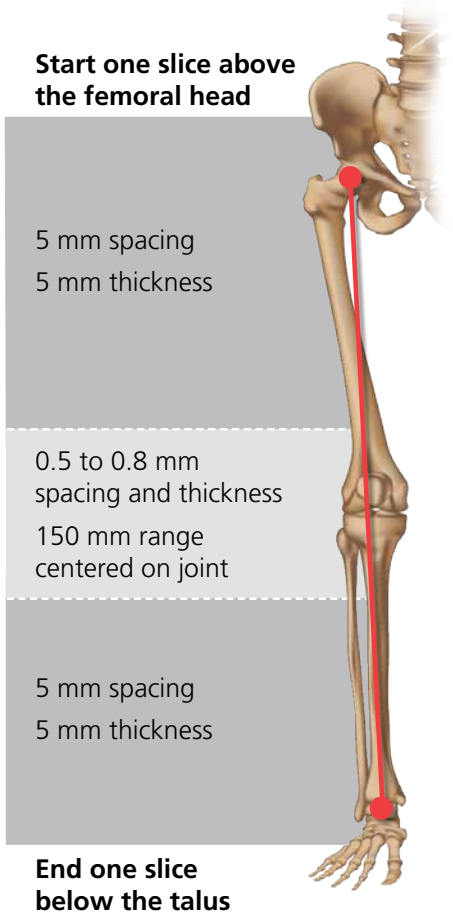
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Scan Parameters

Contrast	Area	FOV	Centers	Spacing/ Thickness	Pitch	kV	Recon Filter
None	Specified Leg	20 cm Max	Constant	Equal see values in Figure 4	1:1	120-140	Soft Tissue

Note: *If your scanner will not support the whole leg in a single study, you may perform three separate studies as shown on the right. Follow these guidelines:*

- *Set the FOV to 20 cm or less on the full leg scout.*
- *Do not change the FOV between studies.*
- *Set the range of the knee study to 150 mm centered on the joint. Do not change the center point between studies.*
- *Adjust the end of the hip study to be the start position of the knee study.*
- *Adjust the start of the ankle study to be the end position of the knee study.*
- *Patient movement between or during the scans will disqualify the study and require rescan.*



SPECIFIED SIDE ONLY

Figure 3

Figure 4

Scanner Specific Parameters

Scanner Brand	Scanner Type	Recon Filter	Knee Slab Thickness/Spacing	Image Transfer Options
Siemens®	Sensation	B31s	0.6 mm	CD-R, DVD-R, MOD, PACS secure DICOM send
GE®	Lightspeed	STANDARD	0.625 mm	CD-R, MOD, PACS secure DICOM send
Philips®	Brilliance	B	0.6 mm or 0.625 mm	CD-R, MOD, PACS secure DICOM send
Toshiba®	Aquilion	FC04	0.5 mm	DICOM send

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GE® is a registered trademark of General Electric Company.
Philips® is a registered trademark of Koninklijke Philips Electronics N.V..
Toshiba® is a registered trademark of Toshiba Corporation.

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Frequently Asked Questions

Are there special instructions if the patient has metal devices in the knee slab region?

Yes, if the patient has an existing implant in the contralateral knee attempt to flex it as to place the metal artifact in slices outside of the knee articular region. Metal in the knee of interest must be at least 8 cm from the knee joint line for the patient to be a candidate for TruMatch Solutions. A scout image will help in identifying patients with metal (see Figure 2).

Should I shift the image center for each slab so each joint is centered in the image?

No, set the field of view (FOV) and image center based on the entire leg and adjust the start and stop locations as necessary.

How should the physical image media (i.e. CD-R) be shipped to DePuy Orthopaedics?

Overnight. The surgeon and patient are counting on the delivery of the scan as soon as possible in order to meet the surgery date. It can also be uploaded per the instructions on the last page.

Should I be concerned about setting windowing for the project?

If you have the ability to adjust the windowing, please use a soft tissue window so that the Hounsfield unit (HU) range is large.

Can I include 5 mm slices through the entire leg and overlap with the thin slices?

No, please follow ranges as specified with minimal or no overlap.

Can I scan the patient in the prone position?

Yes, if necessary due to patient limitations but be sure to label the orientation correctly in your scan and note the prone position on the disk.

Failed CT - does the patient need to be rescanned?

Yes, if the reason for a failed scan is: 1.) Scatter 2.) Movement or 3.) Incomplete set of images (part of the bone was truncated.)

"When a CT fails our protocol, who pays for the second scan?" Example: A patient with existing hardware created scatter and the CT failed.

The CT Center is responsible, especially if they did not follow the protocol or take measures to work around an existing implant.

When can I tell the imaging department that they can erase old CT scans?

CT scans can be erased after the TruMatch website indicates the CT passes.

What mA setting should I use?

CareDose 4D or Smart Dose or any dose controlled method that is enabled by your scanner. Otherwise please determine on a patient specific basis somewhere between 250-400 to maximize image quality while minimizing patient mA dose.

Center Point - What is this? How do I look for it?

This is listed as the X/Y position on some scanners while on others it is listed as A/P, R/L. Do not use just the visualization to see if they are in line but make sure the numbers are correct in all three slabs.

Can the patient be scanned in one single scan then go back in and reprocess the data to 0.5 mm thin slices for 150 mm in the knee joint line and 5 mm slices in the lower and upper leg?

Yes, a single scan can be done but it has to be reprocessed in the three separate spacings that we require in the protocol.

What if a patient cannot straighten his/her leg to get within the 20 cm FOV?

Build up the patient's ankle with a bump (blanket, towel, etc.) so the ankle is in-line with his/her hip.

Is it acceptable to scan a bilateral case together in a 50 cm FOV and reconstruct them separately into 20 cm FOV?

Yes, you can reconstruct a bilateral as long as you make sure that you maintain a FOV of 20 cm or less

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Shipping

CD or DVD - ship *overnight* to:

TruMatch
DePuy Orthopaedics, Inc.
715 Orthopaedic Drive
Warsaw, IN 46582

Secure DICOM send and electronic web upload:

DePuy Orthopaedics is working with Intelemage™, LLC to provide a secure method for automatic DICOM send transmission. An Intelemage™ team member will contact you to begin the registration process. To send images manually, visit our imaging website and follow the instructions for upload: *http://trumatch.secureimagesend.com*

If you would like to contact Intelemage directly, please see their contact information listed below:

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Website: www.intelemage.com

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
USA
Tel: +1 (800) 366 8143
Fax: +1 (574) 371 4865

DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 387 7800
Fax: +44 (113) 387 7890

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0612-04-510 (Rev. 1)

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Exhibit D

Protocol for Landmark Selection

(b)(4) Protocol for Landmark Selection

[redacted]

(b)(4) Protocol for Landmark Selection

(b)(4) Protocol for Landmark Selection

(b)(4) Protocol for Landmark Selection

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Exhibit E

Critical Reference Definitions

Feature	Associated Surgeon Interface Choices	Definitions
(b)(4)		(b)(4)

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(b)(4) Critical Reference Definitions

[redacted]

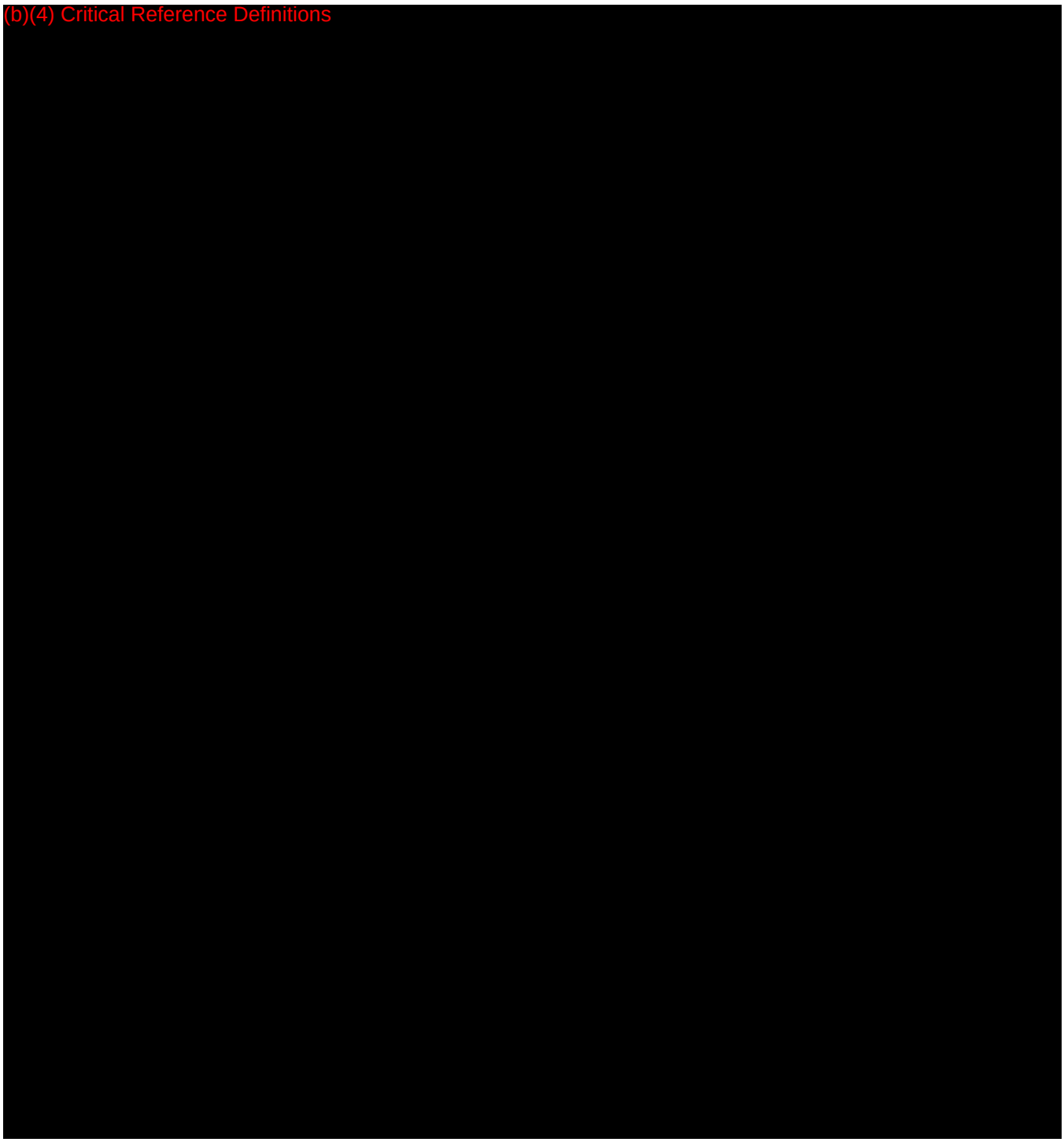
Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4) Critical Reference Definitions

[redacted]

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(b)(4) Critical Reference Definitions



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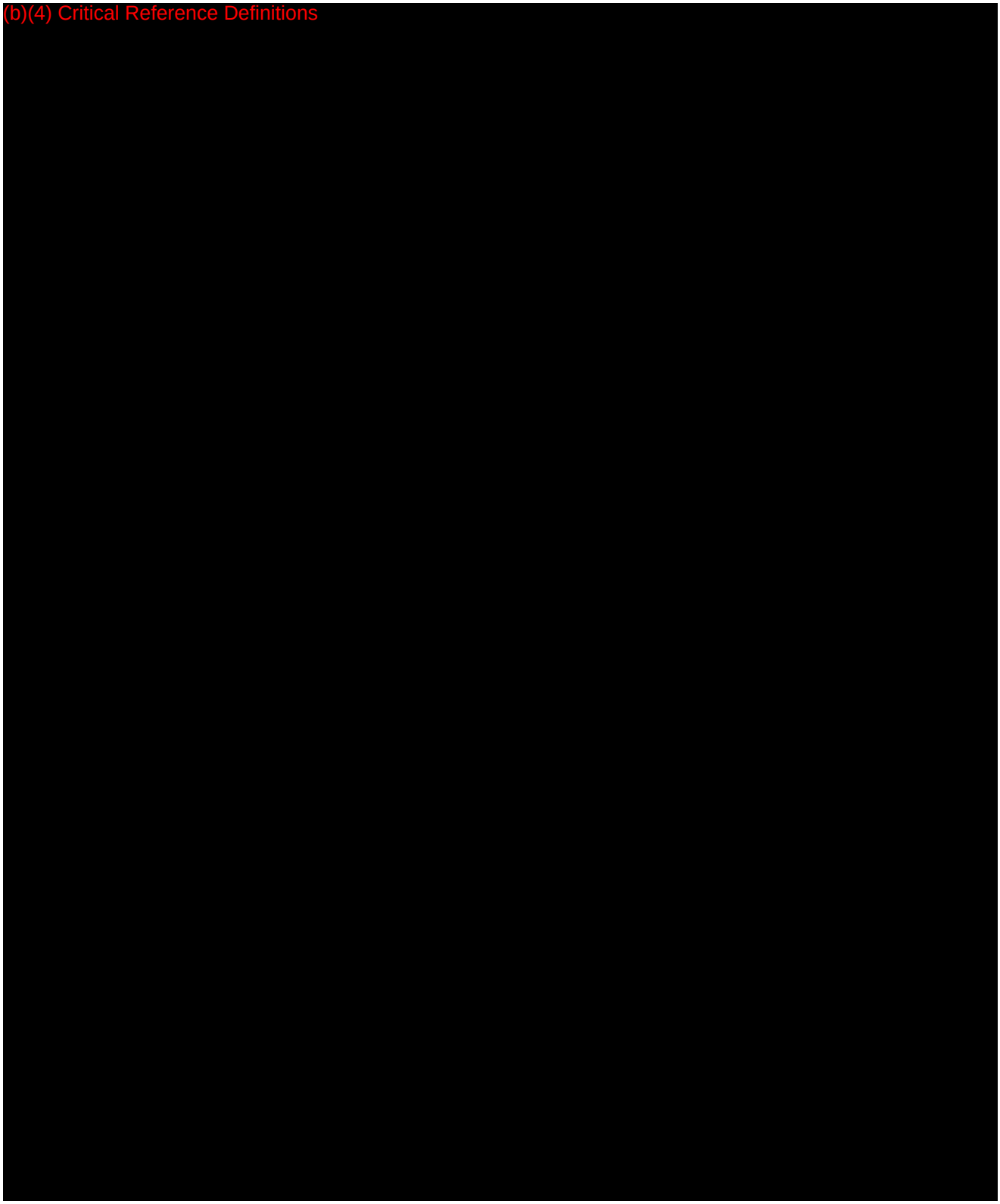
Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4) Critical Reference Definitions

[redacted]

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

(b)(4) Critical Reference Definitions

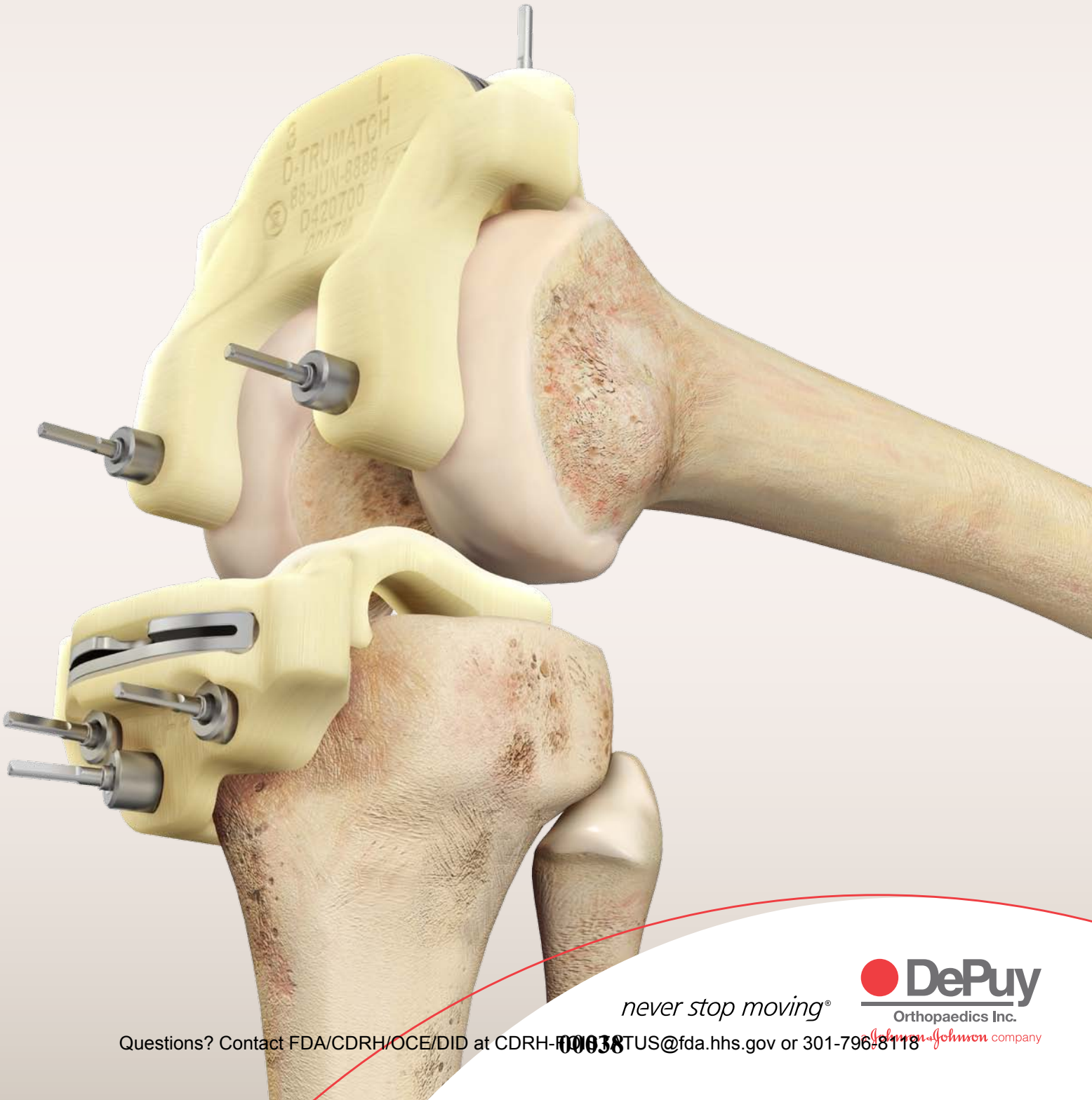


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TruMatch® PERSONALIZED SOLUTIONS | SIGMA® HIGH PERFORMANCE INSTRUMENTS

TRUMATCH® Personalized Solutions Surgical Technique

with the SIGMA® High Performance Instruments System



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The following steps are an addendum to the SIGMA® High Performance (HP) Instruments, Fixed Reference Surgical Technique (Cat. No. 0612-87-510).

This surgical technique provides instruction on how to incorporate the TRUMATCH® femoral alignment/distal and tibial alignment/proximal resection guides into the broader SIGMA HP Instruments Fixed Reference Surgical Technique. As such, the surgeon must be familiar with the proper use of the SIGMA HP Instruments, as these are required in steps prior to, and following, the utilization of the TRUMATCH femoral and tibial resection guides.



TruMatch®
PERSONALIZED SOLUTIONS

Ref. Case #: CP80035M
OrderType: TKA

Confidential Information

Dr. TCEtester2

Please review the following patient proposal. On your DePuy TruMatch website use the "Make Decision" button to select the appropriate status for this case. Once your approval and feedback has been submitted, manufacturing of the custom guides will begin.

Please contact DePuy TruMatch Support if you have any questions or need further information.

Toll Free number: 1-800-689-0746
E-mail: TruMatchSupport@depuy.jnj.com

Cordially,

DePuy Orthopaedics, Inc.

DePuy Orthopaedics - TruMatch Design Team

Patient Name: [redacted]
Gender: M DOB: 1945-01-12 Height: 5 ft, 10 in Weight: 220 lb Affected Side: L
Patient Special Considerations:
Profile: Varus Cartilage Loss: M: 100% L: 75% Surgery Date: 2011-01-07

Surgeon Name: [redacted] Facility: St. Mary 's
Contact Email: [redacted]

Device Information:
Implant System: PFC Sigma Instrument System: HP
Fem. Component: Sz 6 PS L Poly Component: Sz 6 Tib Component: Fixed Bearing

Alignment: (NOTE: All TruMatch resections are planned with varus/valgus angle perpendicular to the mechanical axis)
Fem. Sizing Ref.: Anterior Down External Rotation Ref.: Posterior Condyles External Rot.: 0°
Distal Fem. Resect: 5.0 + 1.0 = 6.0 Distal Resection Ref: Mechanical Axis Valgus Rot.: 0°
Prox. Tib. Resect: 5.0 + 0.0 = 5.0 Posterior Tib. Slope: 0°

Notes/Comments:

Proposal Revision: 2

Upon your approval, DePuy will manufacture the customized instruments based upon the listed information supplied by you. DePuy has not verified the information supplied by you and makes no warranty as to the correctness or applicability of such information in the customized instruments to be manufactured or supplied pursuant to your request and therefore makes no warranty and disclaims an implied warranty of merchantability or fitness for a particular purpose with respect to the customized instruments. DePuy also expressly warrants that the customized instruments to be supplied under this request was merchantable, of good quality and free from defects, whether patent or latent, in material, or workmanship; and that the customized instruments sold hereunder conform to or exceed the highest grading standards recognized by DePuy or industry. DePuy further warrants that it has good title to the customized instruments and that the customized instruments are free and clear from all liens and encumbrances.

Page 1 of 2

The surgeon must also carefully review the TRUMATCH Patient Proposal prior to proceeding with the surgical procedure. The Patient Proposal is available through the web-based, password protected, TRUMATCH Personalized Solutions portal.

The Patient Proposal contains in-depth information utilized in the design of the patient specific guides including, as necessary, requests that are listed in the Notes/Comments section.

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

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Basic TRUMATCH® Surgical Steps

Femoral Preparation



Step 1: Femoral block positioning



Step 2: Placement of anterior pins



Step 3: Drill and placement of distal pins



Step 4: Distal femoral resection



Step 5: Use of the fixed reference guide to position the 4-in-1 chamfer block

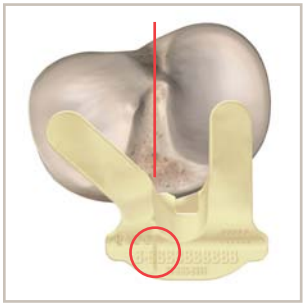


Step 6: Use of the angelwing to verify anterior resection.



Step 7: Placement of chamfer block pins and removal of the fixed reference guide

Tibial Preparation



Step 1: Tibial block placement aided by patient proposal



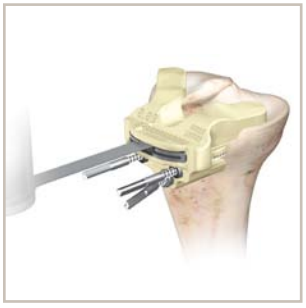
Step 2: Placement of two anterior pins



Step 3: V/V verification with alignment adapter and rod



Step 4: Placement of divergent, locking pin



Step 5: Tibial plateau resection

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Distal Femoral Resection

The femoral alignment/distal resection guide (as well as the packaging the guide comes in) will have patient specific identifiers: Patient Name, Patient D.O.B., Size and Patient Anatomy (R/L). Please verify the accuracy of these identifiers prior to use (Figure 1).

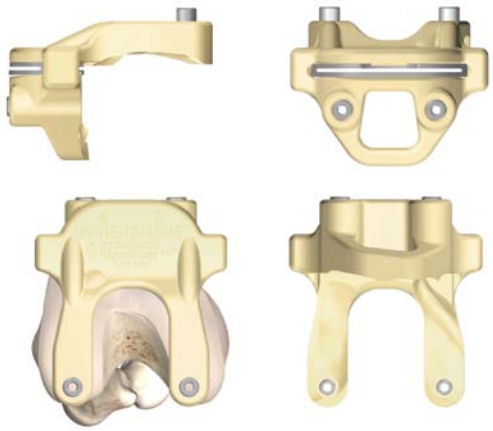


Figure 1

Place the femoral alignment/distal resection guide onto the distal aspect of the femur while in flexion of approximately 90 degrees (Figure 2). Due to the large amount of contact area between the guide and the bone, it may be easier to position the guide by seating the anterior aspect of the guide on the anterior cortex first (Figure 2 - lower left) and then toggle the device posteriorly. Avoid using excessive force to seat the guide, as it is not needed.

Note: *It may be necessary to clear extraneous tissue along the anterior cortex as this may cause the guide to not seat properly. Be careful to avoid any soft tissue impingement, as this will impact the overall alignment of the resection guide. Better visualization of the proper seating may be possible if the guide is viewed from a sagittal viewpoint. See the Surgical Tips and Pearls section for further information.*

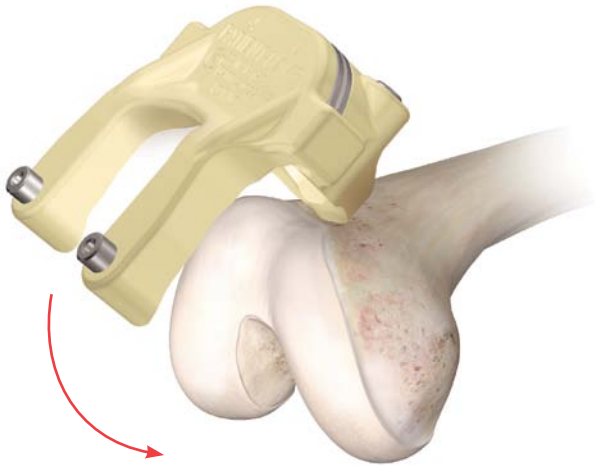


Figure 2

Once the optimum position is found for the femoral alignment/distal resection guide, see that it allows no toggling or rocking. It is not uncommon to see a 2 to 3 mm gap around the periphery of the guide due to cartilage loss.

When placement is optimized, secure the femoral alignment/distal resection guide by inserting one threaded 3.25 mm pin through the anterior medial hole (Figure 3). After the medial pin is secured, place another pin through the lateral pin hole (Figure 3).



Figure 3

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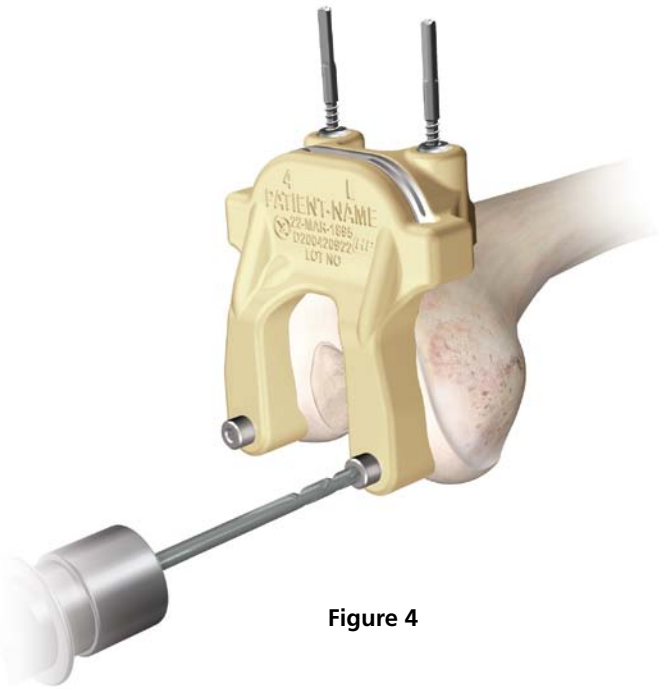


Figure 4

After the femoral alignment/distal resection guide is secured, drill the two distal holes with a 3.25 mm drill bit. These pin holes set the femoral rotation and match the A/P chamfer block from the standard instrument set (Figure 4).

Prior to cutting, the pin may be removed. However, it is recommended to perform the distal femoral resection by leaving one distal pin in the block while resecting the opposite side of the femur.



Figure 5

Perform the distal femoral resection with a 1.19 mm blade (Figure 5).

Remove femoral alignment/distal resection guide. Make sure bone cuts are clean and void of any under-cut bone fragments.

Note: *In order to adjust ligament tension, it may be necessary to re-cut the distal aspect of the femur or the proximal aspect of the tibia to achieve proper balance. In these instances, the anterior location of the pins are compatible with the regular HP Instruments distal femoral cutting or tibial resection guides. Both guides can be used to cut either 2 or 4 mm of additional bone. These guides fit over pins placed in the previously drilled guide pin locations.*

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Femoral Preparation - A/P and Chamfer Cuts

Attach the Universal Handle to the Fixed Reference Guide (Cat. No. 2004-20-920) and position the guide's spikes on the 0 mm pinholes of the SIGMA Fixed Reference A/P chamfer block (Figure 6). Once the handle/guide/ block assembly is put together, insert the guide's spikes into the existing holes located on the distal femoral bone cut.

Note: *The TRUMATCH femoral block is designed to position the pin holes posteriorly while maintaining the desired "anterior down" or "posterior up" fixed reference selection. In addition, the SIGMA RP-F, SIGMA CR-150 and standard SIGMA A/P and chamfer cutting blocks look very similar. Care should be taken to use the appropriate block as this could result in under or over resection of the posterior condyles.*

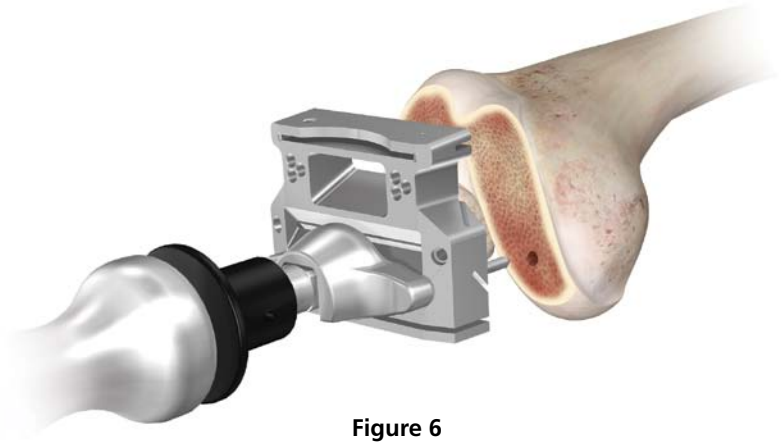


Figure 6

Confirm the anterior cut placement with the reference guide, or angelwing (Figure 7). If desired, the block may be shifted 2 mm anteriorly or posteriorly by selecting one of the offset holes around the "0" hole. When downsizing, using the smaller A/P chamfer block and the most anterior pin holes will take 2 mm more bone anteriorly and 2 mm less bone posteriorly.

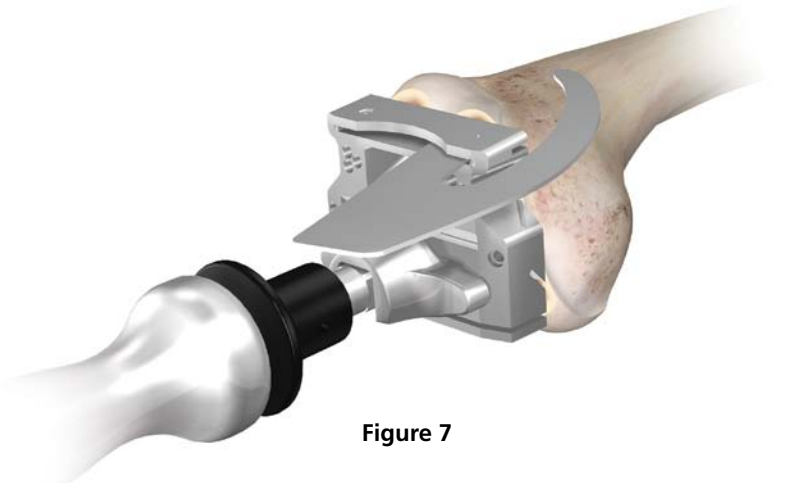


Figure 7

Secure the block's location by inserting threaded headed pins into the convergent pin holes on the medial and lateral aspect of the A/P chamfer block. Once completed, remove the handle/ fixed reference guide assembly and perform the femoral chamfer cuts in the regular manner (Figure 8).

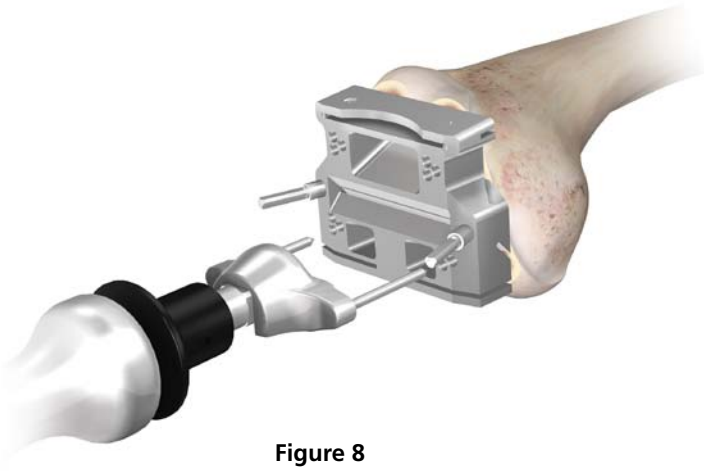


Figure 8

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Proximal Tibial Resection

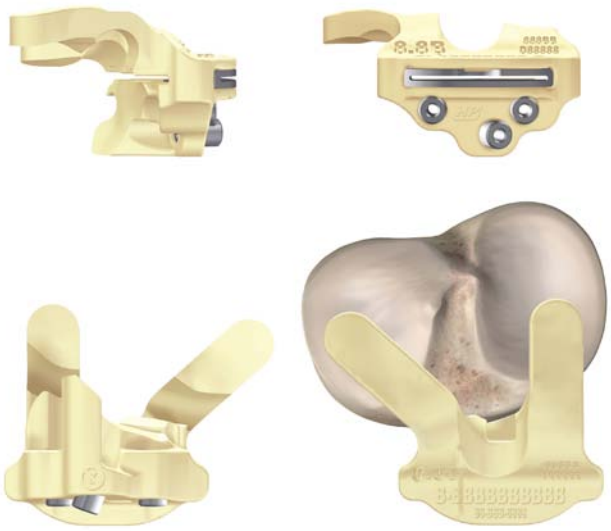


Figure 9

The tibial alignment/proximal resection guide (as well as the packaging the guide comes in) will have patient specific identifiers: Patient Name, Patient D.O.B., Size and Patient Anatomy (R/L). Please verify the accuracy of these identifiers prior to use (Figure 9).

Place the tibial alignment/distal resection guide onto the proximal aspect of the tibia while in flexion of approximately 90 degrees. Avoid using excessive force to seat the guide, as it is not needed. To assist in the M/L positioning of the tibial resection guide, the last page of the Patient Proposal document contains a top view of the tibial surface. As shown in the Proposal's patient specific view, align the line on top of the tibial resection guide with the one displayed on the tibial bone (Figure 10).

Note: *It may be necessary to clear extraneous tissue along the anterior aspect of the tibia as this may cause the guide to not seat properly. Be careful to avoid any soft tissue impingement, as this will impact the overall alignment of the resection guide. Better visualization of the proper seating may be possible if the guide is viewed from a sagittal viewpoint.*

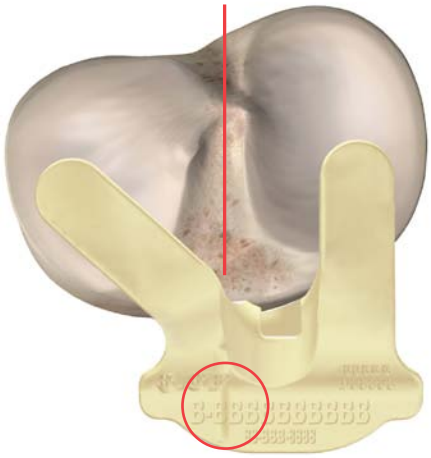




Figure 11

To position the guide, it is helpful to apply approximately 25 percent pressure to the proximal aspect and 75 percent pressure to the anterior aspect of the guide. This will aid in seating the guide to arrive at the appropriate resection level. Once the optimum position is found for the tibial alignment/proximal resection guide, see that it allows little to no toggling or rocking.

When placement is optimized, secure the resection guide by inserting one non-headed threaded 3.25 mm pin through the medial hole. After the medial pin is secured, place another pin through the lateral pin hole (Figure 11).

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Proximal Tibial Resection (continued)

After selecting the proper R/L orientation of the Alignment Verification Adapter (Cat. No. 2000-42-062) (holes point laterally) insert one of the two HP Alignment Rods. Then, insert the adapter's blade into the resection guide's saw slot (Figure 12).



Figure 12

Confirm the Varus/ Valgus (V/V) position of the guide by verifying that the rod distally lies along, or parallel to, the patient's tibial crest. If the V/V alignment is not acceptable, check for proper seating, soft tissue impingement or proper M/L orientation of the resection guide. If necessary, remove the fixation pins and reposition the resection guide following the steps previously described. See Surgical Tips and Pearls section for further information.

Once the V/V alignment of the resection guide is satisfactory, insert an additional pin in the distal hole. This hole will place the pin in a divergent path to add stability (Figure 13).



Figure 13

Note: *Optionally, the tibial resection guide can be V/V aligned and fixed by a) positioning it M/L, as described, aided by the image in the Patient Proposal; b) inserting only the medial fixation pin; c) utilizing the alignment adapter/rod assembly, verify the V/V alignment of the guide d) manually holding the guide and inserting the remaining two fixation pins.*

Perform the proximal tibial resection with a 1.19 mm blade (Figure 14).

After removing all fixation pins and the tibial resection guide, make sure bone cuts are clean and void of any under-cut bone fragments.



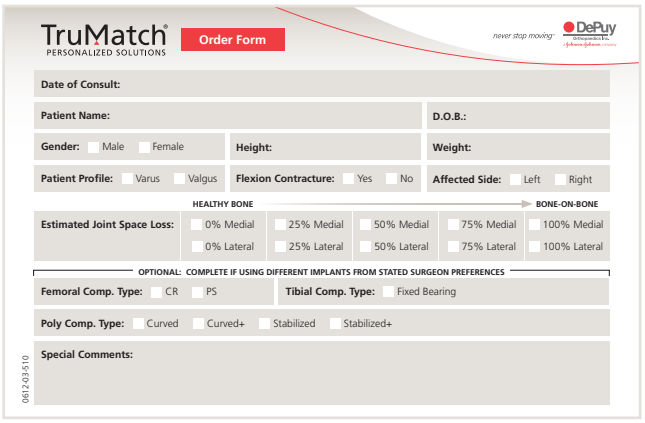
Figure 14

Note: *If additional tibial resection or tibial slope is desired, replace the two proximal fixation pins and utilize the appropriate SIGMA HP Instrument's tibial resection guide.*

Proceed with the remaining steps for proximal tibial preparation as outlined by the SIGMA HP Instruments Surgical Technique.

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Order Form

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Date of Consult:

Patient Name: D.O.B.:

Gender: Male Female Height: Weight:

Patient Profile: Varus Valgus Flexion Contracture: Yes No Affected Side: Left Right

HEALTHY BONE → BONE-ON-BONE

Estimated Joint Space Loss:	0% Medial / 0% Lateral	25% Medial / 25% Lateral	50% Medial / 50% Lateral	75% Medial / 75% Lateral	100% Medial / 100% Lateral

OPTIONAL: COMPLETE IF USING DIFFERENT IMPLANTS FROM STATED SURGEON PREFERENCES

Femoral Comp. Type: CR PS Tibial Comp. Type: Fixed Bearing

Poly Comp. Type: Curved Curved+ Stabilized Stabilized+

Special Comments:

0612-03-510

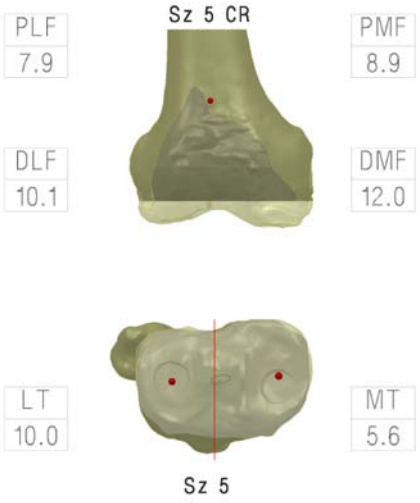


Figure 15

PREOPERATIVE

Order Form

a. Take careful consideration when estimating the M/L "Joint Space Loss" by utilizing weight bearing knee joint radiographs and providing it with the order submission. This value is an important part of the algorithm used to design the cartilage offset for proper positioning of the blocks.

Patient Proposal

a. Review in detail prior to the surgery.

b. Review the Notes/Comments section for information from the TRUMATCH design team regarding the design of the blocks.

c. Print in Color! All Notes/Comments will be shown in red.

d. For intraoperative reference, display at an easy to read area in the OR, such as the light box or back wall.

e. Review the intraoperative check-list (last page), which contains bone resection information and tibial block orientation view (Figure 15).

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

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INTRAOPERATIVE

Fixation Pins

a. The SIGMA HP threaded, headless and sterile pins (9505-02-302), combined with the HP driver (9505-02-071), are recommended for firmly securing the blocks, especially for the tibial block when used on soft bone.

Femoral Resection Block

a. The femoral block's primary reference surface is the anterior cortex of the femur (Figure 16a). The upper most portion of the block should clear the anterior femoral flange and sit flush on the bone cortex. It may be necessary to remove the thin soft tissue to expose the underlying bone. When positioning the block, apply most of the pressure (~75%) against the anterior aspect of the femur.

b. Distally, a gap may be seen between the block and the femoral condyles (Figure 16b). If the block is securely positioned anteriorly, do not force the block's arms to sit flush on the femoral condyles. While applying anterior force apply light force (~25%) distal-to-proximal, to stabilize the block. Secure it by inserting the anterior fixation pins.

c. After performing the distal femoral resection and removing the block, examine the posterior aspect of the block's arms. If it appears to be damaged by the saw blade, that respective condyle cut was likely under cut and out of plan. The block should be repositioned and the cut repeated (Figure 17).

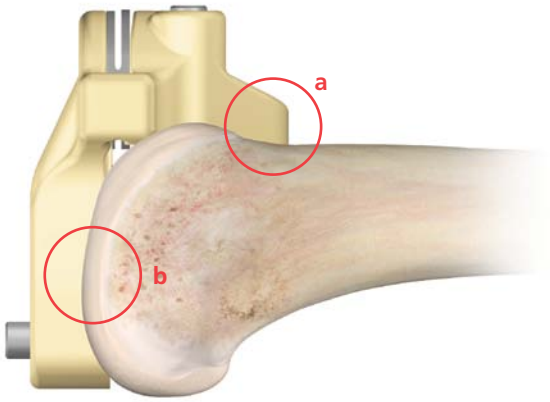


Figure 16

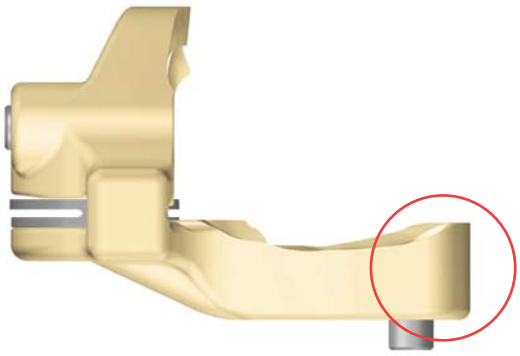


Figure 17

If the femoral block does not fit, verify the following:

1. Was the tissue in the anterior surface of the femur removed and is the proximal portion of the block sitting on bone?
2. Did the block upper portion clear the anterior femoral flange and is it sitting on the bone cortex?
3. Is the incision preventing placement of the block on the bone? The incision must provide a clear view of the block fit to bone.

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Figure 18

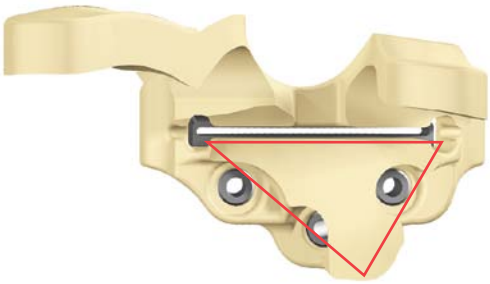


Figure 19

Tibial Resection Block

a. The tibial block's primary reference surface is the anterior/medial aspect of the tibia. This area, roughly triangular in shape, matches the block's largest surface contact area located below the saw slot (Figure 18). When positioning the block, apply most of the pressure (~75%) against the anterior aspect of the tibia. It may be necessary to remove the thin soft tissue to expose the underlying bone (Figure 19).

b. If the block is securely positioned anteriorly, do not force the block's arms to sit flush on the tibial plateau. While applying force anteriorly, apply light downward force (~25%) on the block's proximal arms to hold the block stable. Secure it by inserting the anterior fixation pins.

If the tibial block does not fit, verify the following:

1. Is the incision preventing placement of the block on the bone? The incision must provide a clear view of the block fit on the bone.
2. Check that the lateral aspect of the block is not sitting on the patellar tendon.
3. Confirm that both of the block's proximal arms are not impinged by tissue close to the tibial spine.
4. Check the Patient Proposal, was the "Joint Space Loss" reported to be 100% for either of the condyles, although the actual patient has little to no joint space loss? If so, scrape the condyle where full joint loss was requested.

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The TRUMATCH Personalized Solutions system is currently targeted for patients with osteoarthritis who:

1) Meet the criteria for primary total knee replacement performed with a measured resection technique.

2) Have mild bone deformities and/or angular deformities less than 15 degrees of fixed varus, valgus, or flexion.

Some previous implants are acceptable, including hip implants, ankle implants, and soft tissue anchors. Contralateral knee replacement is acceptable as long as the contralateral knee is flexed away (not within the same medial/lateral axis) from the knee of interest during the CT scan. Please refer to the TRUMATCH CT Center User Guide for more information.

EXCLUSION CRITERIA:

The following conditions are not compatible with TRUMATCH Personalized Solutions:

- Previous knee replacement of the same knee.
- Femoral nails and bone plates that extend into the knee, or 8 cm from the joint line.
- Any metal device that will cause scatter in the CT through the knee.
- Angular deformities greater than 15 degrees of fixed varus, valgus, flexion, or tibial slope exceeding 15 degrees.
- Moderate to severe bony deformities, charcot knees, or patients with severe patella tendon calcification that may prevent patella eversion.

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
USA
Tel: +1 (800) 366 8143
Fax: +1 (574) 267 7196

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Design Verification Testing Protocol/Report

(b)(4) Design Verification Testing Protocol/Report

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TECHNICAL MEMORANDUM

TO: FILE

FROM: (b)(6) SENIOR PROJECT ENGINEER (X 5957) (b)(6) 30 Jul 08

SUBJECT: (b)(4) Testing

DATE: DECEMBER 14, 2007

INTRODUCTION

(b)(4) Testing

METHODS AND MATERIALS

(b)(4) Testing

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(b)(4) Testing

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(b)(4) Testing

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R&D TEST REPORT

SUBJECT: (b)(4) ACCURACY AND (b)(4) TEST

AUTHOR: (b)(6) SENIOR PROJECT ENGINEER (X 5957)

WORK DONE BY: (b)(6) 5 AUG 2010 (b)(6) 5 AUG 2010

PROJECT NO: (b)(4)

DATE: 28 JULY 2010

(b)(4) Testing

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(b)(4) Testing

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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 F899-09 : Standard Specification for Wrought Stainless Steels for Surgical Instruments

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-181	
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 the standard? 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], www.fda.gov/cdrh/stdsprog.html

[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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F899-09 : STANDARD SPECIFICATION FOR WROUGHT STAINLESS STEELS FOR SURGICAL INSTRUMENTS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Classification and Type	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
Class 5 - Precipitation Hardenable Stanless Steel selected. UNS S17400 Type 630 selected

DESCRIPTION
Selection of Class, Unified Numbering System (UNS) Designation, and Type of material

JUSTIFICATION
N/A

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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510(k) Summary

Applicant / Sponsor:	DePuy Orthopaedics Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration No.: 1818910
Contact Person:	Nancy S. Friddle Project Manager, Regulatory Affairs Tel: (574) 371-4923 Fax: (574) 371-4987
Proprietary Name:	TruMatch™ Personalized Solutions
Common Name:	Total Knee Prosthesis
Classification Name**:**	21 CFR 888.3560: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. Class II
Product Code:	JWH
Subsequent Product Code:	OOG

Device Description:

Subject of this premarket notification are TruMatch™ Patient Specific Instruments which are designed and manufactured from patient imaging data and used with other DePuy Orthopaedics implants.

Indications and Intended Use:

The TruMatch™ Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The anatomical landmarks necessary for the creation of the TruMatch™ Patient Specific Instruments must be present and identifiable on CT.

The TruMatch™ Patient Specific Instruments are intended for use with Sigma® Total Knee Implants and Attune™ Total Knee Implants and their cleared indications for use.

The TruMatch™ Patient Specific Instruments are intended for single use only.

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Summary of Technologies/Substantial Equivalence:

The TruMatch™ Patient Specific Instruments have the same indications, intended use, similar design and are substantially equivalent to the Smith & Nephew's Patient Matched Cutting Blocks and also to the traditional instruments that are associated with the Sigma® and Attune™ cleared knee implant systems. The TruMatch™ Patient Specific Instruments are used in conjunction with the DePuy Orthopaedics, Inc Sigma and Attune implant systems identified in the table below.

System	510k	Clearance Date
Sigma Total Knee System	K882234	10/20/1988
	K884796	3/29/1989
	K943462	12/21/1994
	K950010	5/15/1995
	K944538	9/26/1995
	K961685	7/10/1996
	K961685	7/10/1996
	K971189	7/17/1997
	K971189	7/17/1997
	K082500	11/18/2008
Attune Total Knee System	K101433	12/10/2010

Non-Clinical Testing:

The following testing was performed to demonstrate the substantial equivalence of the TruMatch™ Patient Specific Instruments to the predicate devices.

- TruMatch™ Dimensional Stability Test
- Cadaver Accuracy Study
- Design Process and Design Software Repeatability Study
- Software Validation and Verification Summary

The tests results demonstrate that all acceptance criteria were met.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the TruMatch™ Patient Specific Instruments and the predicate devices.

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THE INTERNATIONAL JOURNAL OF MEDICAL ROBOTICS AND COMPUTER ASSISTED SURGERY
Int J Med Robotics Comput Assist Surg 2008; **4**: 224–231.
Published online 4 August 2008 in Wiley InterScience (www.interscience.wiley.com). **DOI:** 10.1002/rcs.201

ORIGINAL ARTICLE

Accuracy of MRI vs CT imaging with particular reference to patient specific templates for total knee replacement surgery

D. White*
K. L. Chelule
B. B. Seedhom

Division of Bioengineering, Academic Unit of Musculoskeletal Diseases, Leeds Medical School, University of Leeds, UK

*Correspondence to: D. White, Division of Bioengineering, Academic Unit of Musculoskeletal Diseases, Leeds Medical School, University of Leeds, UK. E-mail: d.m.white@leeds.ac.uk

Abstract

Background The present study compares the accuracy of MRI and CT imaging for the manufacture of patient-specific templates for total knee replacement surgery.

Methods A total of 10 ovine knees were imaged using MRI and CT scanners. Each set of images was reconstructed in 3D and then used to manufacture physical models of each bone, using rapid prototyping technology. After imaging the soft tissues were removed and specific measurements of the bony anatomy compared with measurements from the MRI and CT models.

Results Bone models generated from MRI scans were dimensionally less accurate than those generated from CT scans. Furthermore, the bone models generated from MRI scans were visibly inferior to those generated from the CT scans.

Conclusions Current MRI scans do not offer a viable alternative to CT. Although adaptation of the template system to accommodate MRI imaging is possible, the changes required are neither practical nor desirable. Copyright © 2008 John Wiley & Sons, Ltd.

Keywords total knee replacement; computed tomography; magnetic resonance imaging; rapid prototyping; patient-specific templates

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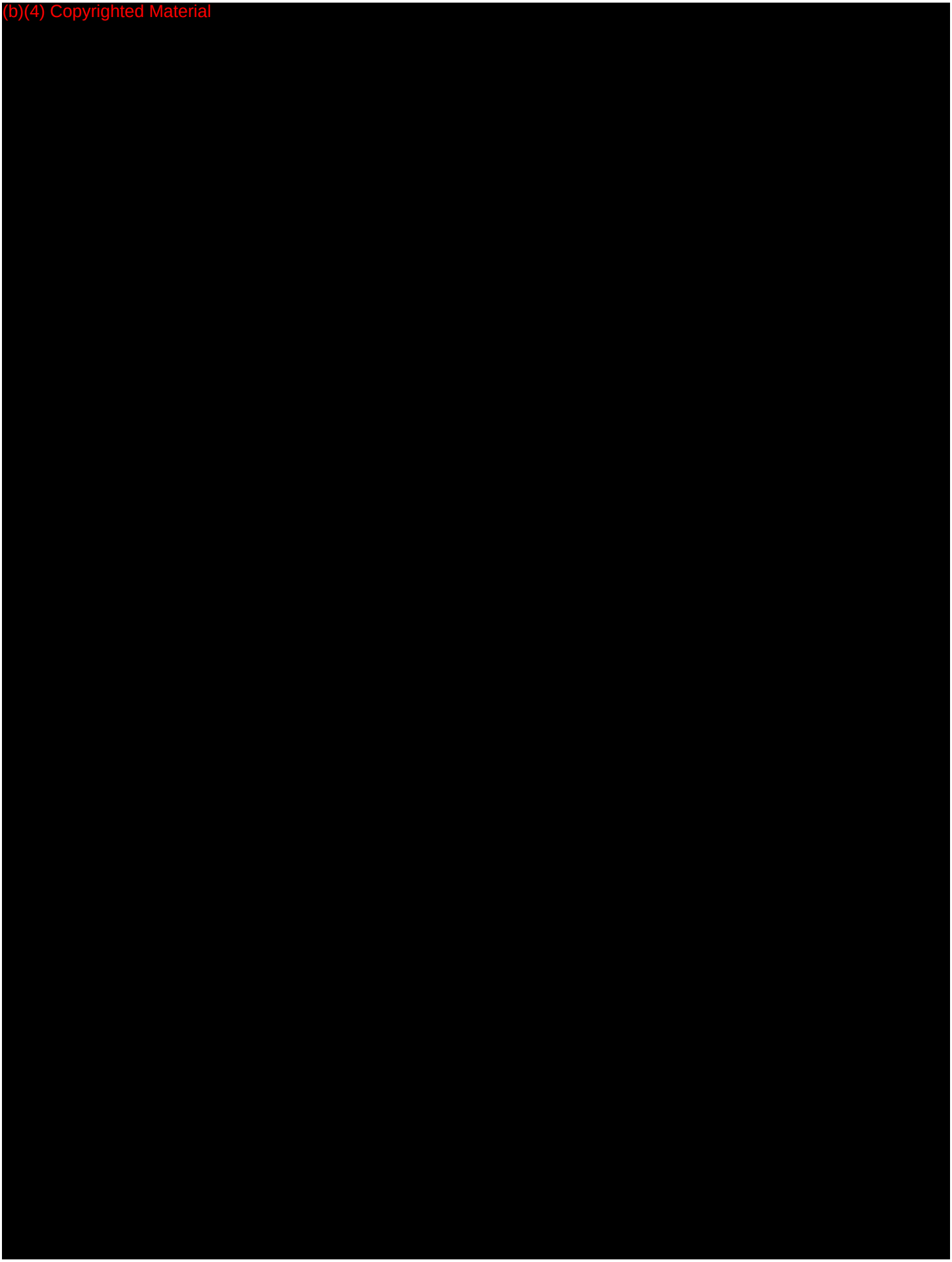
Accepted: 3 June 2008

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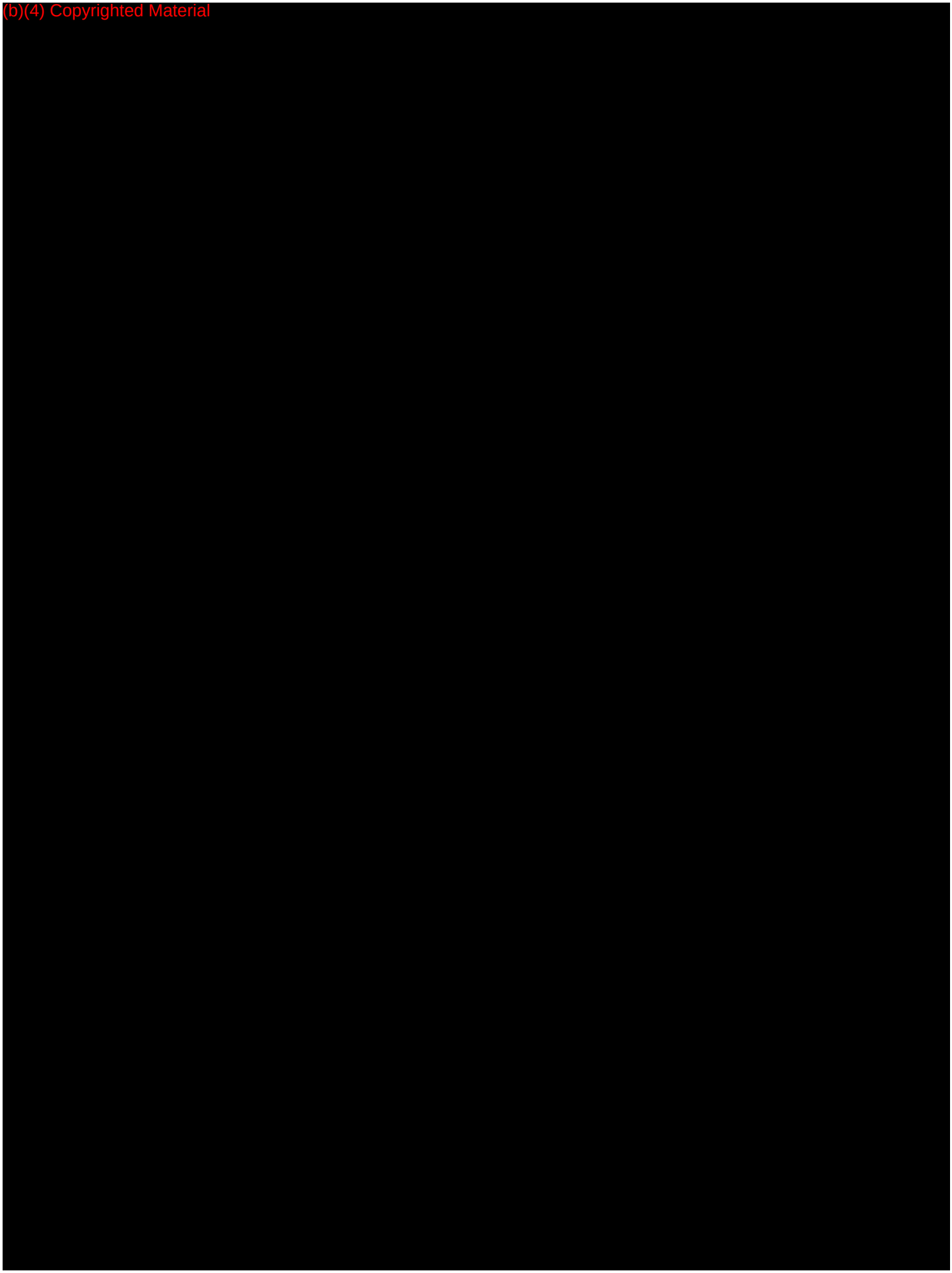


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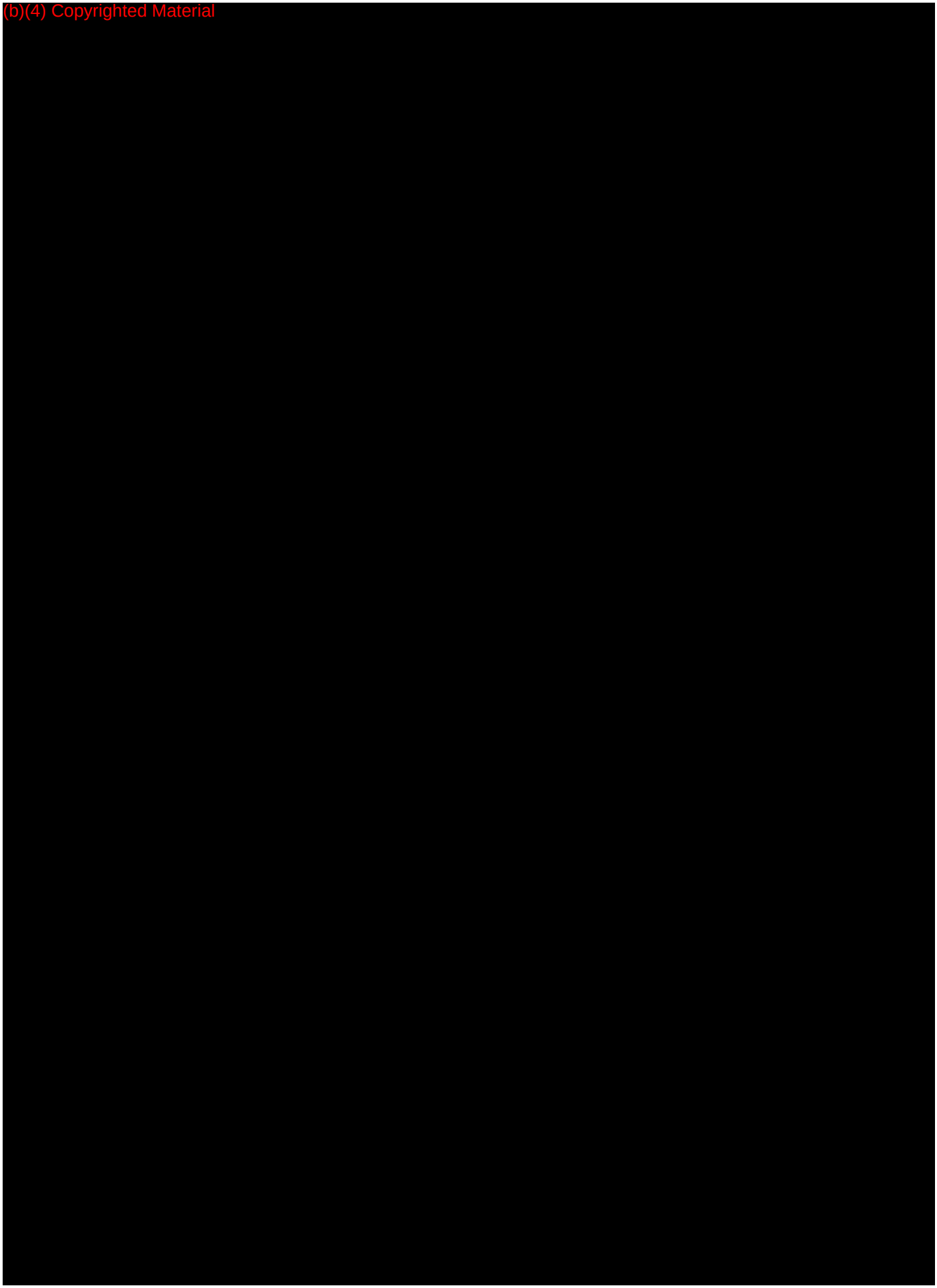
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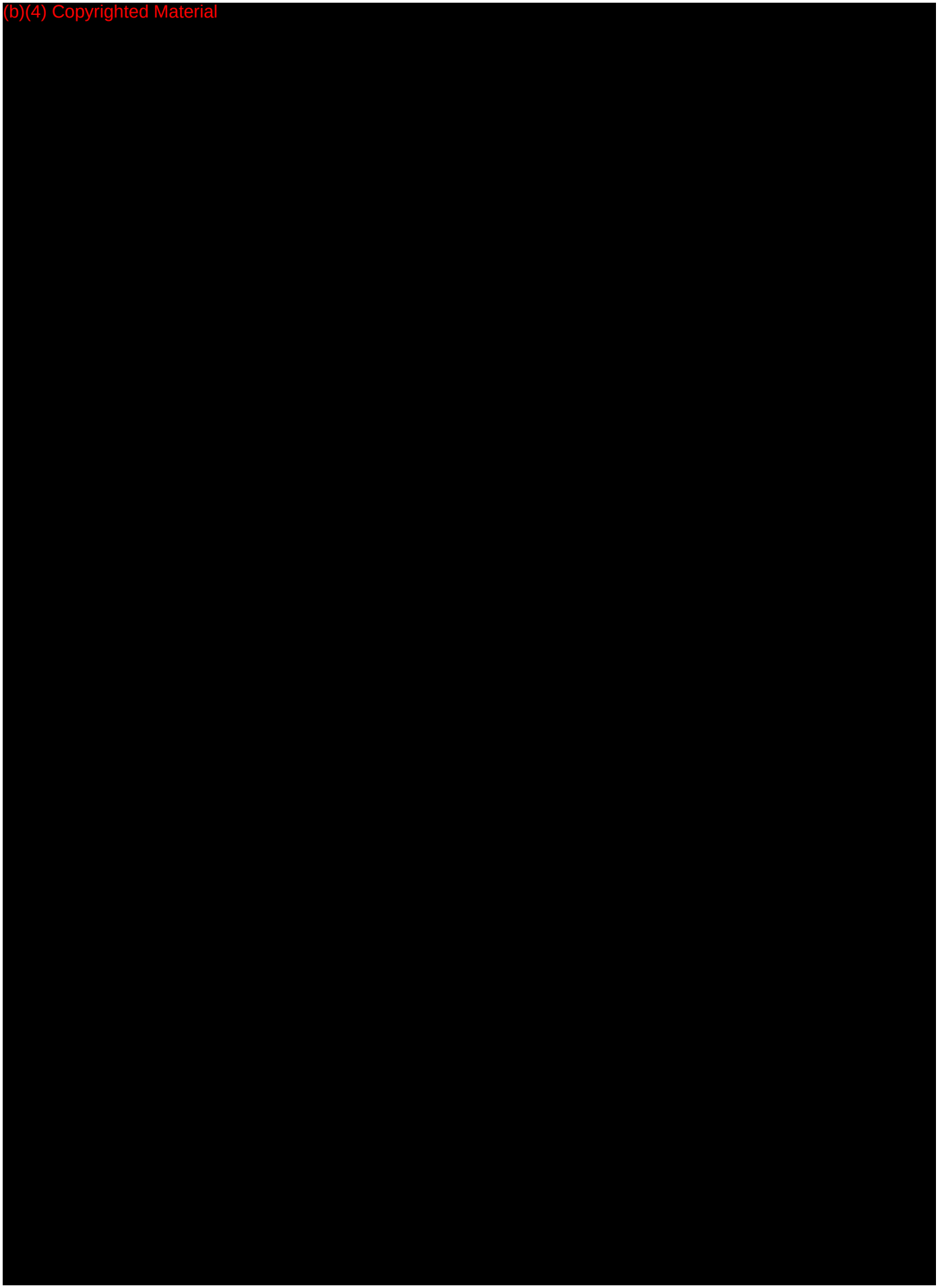
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The Journal of Arthroplasty Vol. 15 No. 3 2000

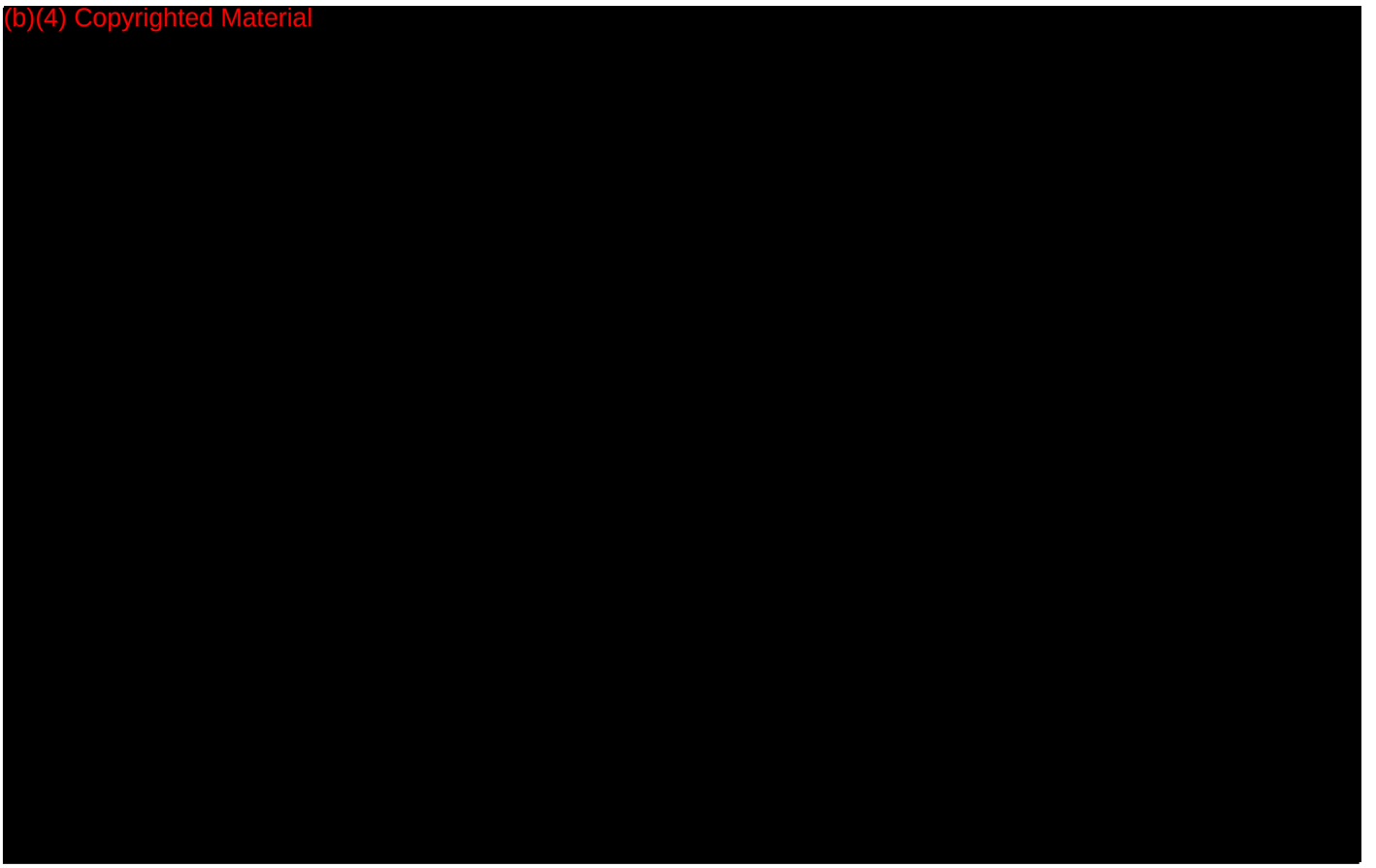
Anatomy of the Epicondyles of the Distal Femur

MRI Analysis of Normal Knees

Frankie M. Griffin, MD,* Kevin Math, MD,† Giles R. Scuderi, MD,‡
John N. Insall, MD,‡ and Pascal L. Poilvache, MD§

Abstract: Knowledge of precise anatomic landmarks and relationships of the distal femur can be helpful in knee surgery, especially primary and revision total knee arthroplasty. We analyzed 104 consecutive routine knee magnetic resonance imaging studies to define useful landmarks and relationships. The epicondyles are described, and the relationship of the epicondyles to the joint line is defined in multiple planes. Some significant gender differences were noted. The distance from the epicondyles to the joint line correlates with the transepicondylar width of the distal femur. This information can be helpful in determining appropriate joint line position intraoperatively. The posterior condylar angle averaged 3.11° for all patients, and a tendency for the posterior condylar angle to increase with age was noted, but further study of this tendency is needed. **Key words:** total knee arthroplasty, epicondyles, anatomy, distal femur, posterior condylar angle.

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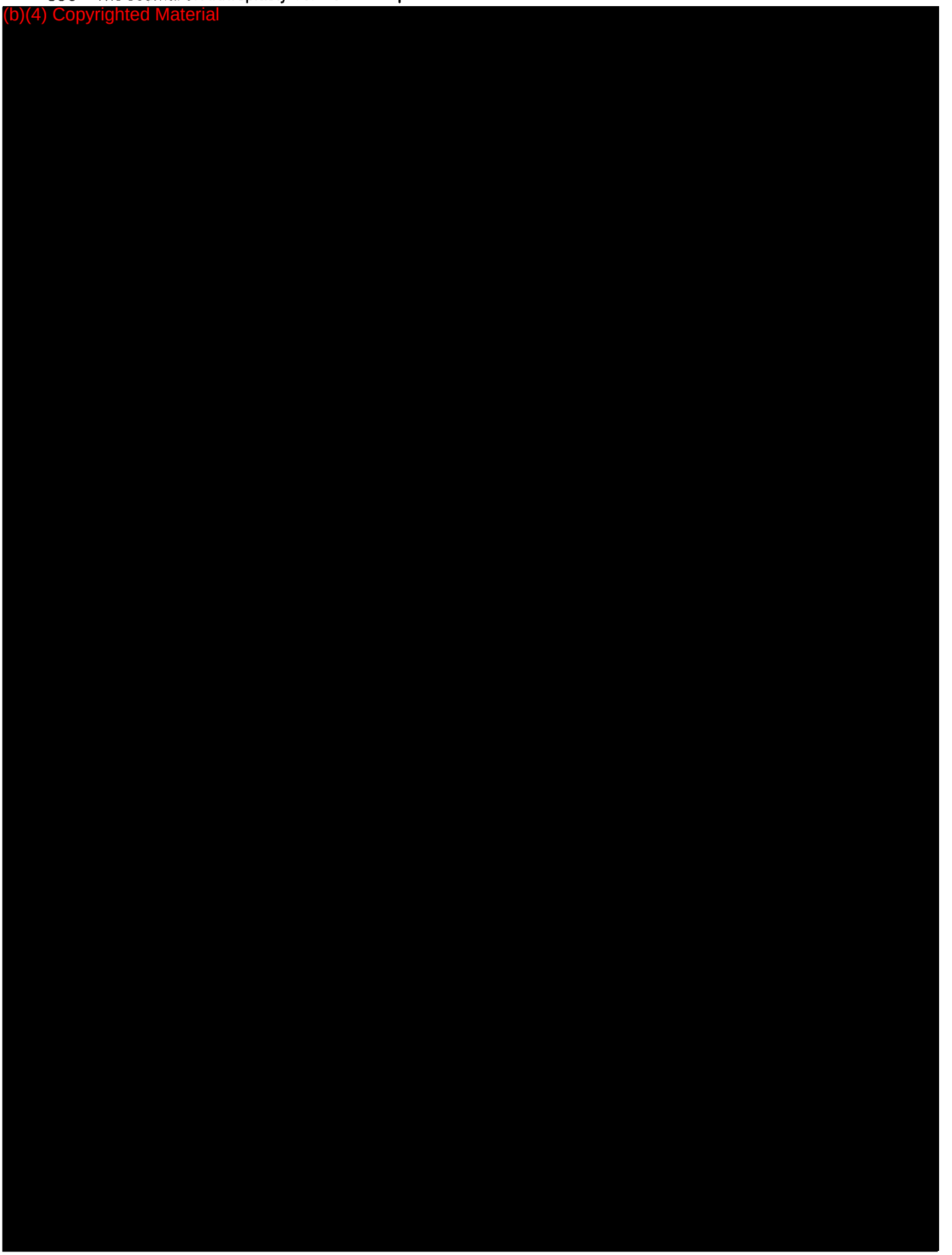
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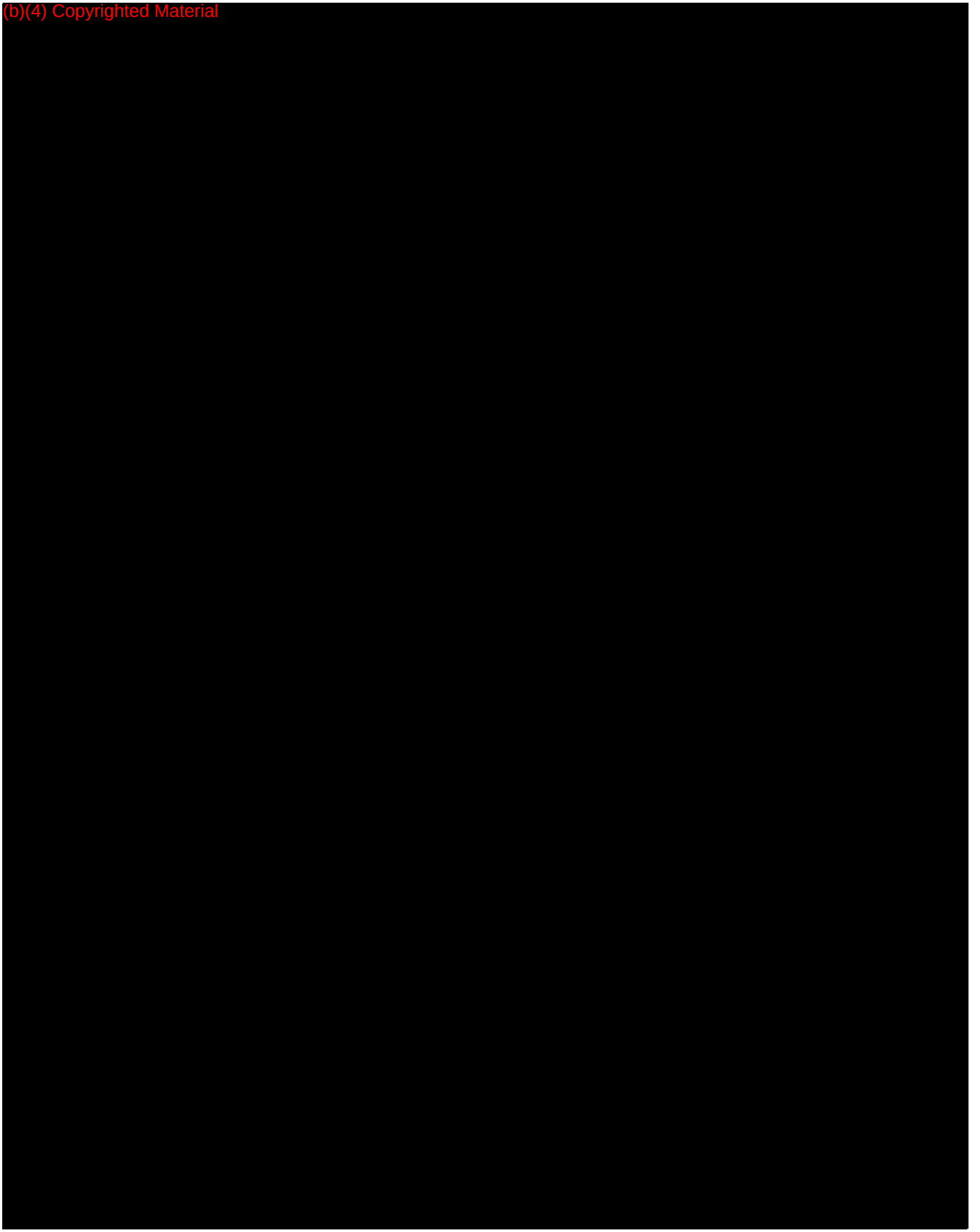
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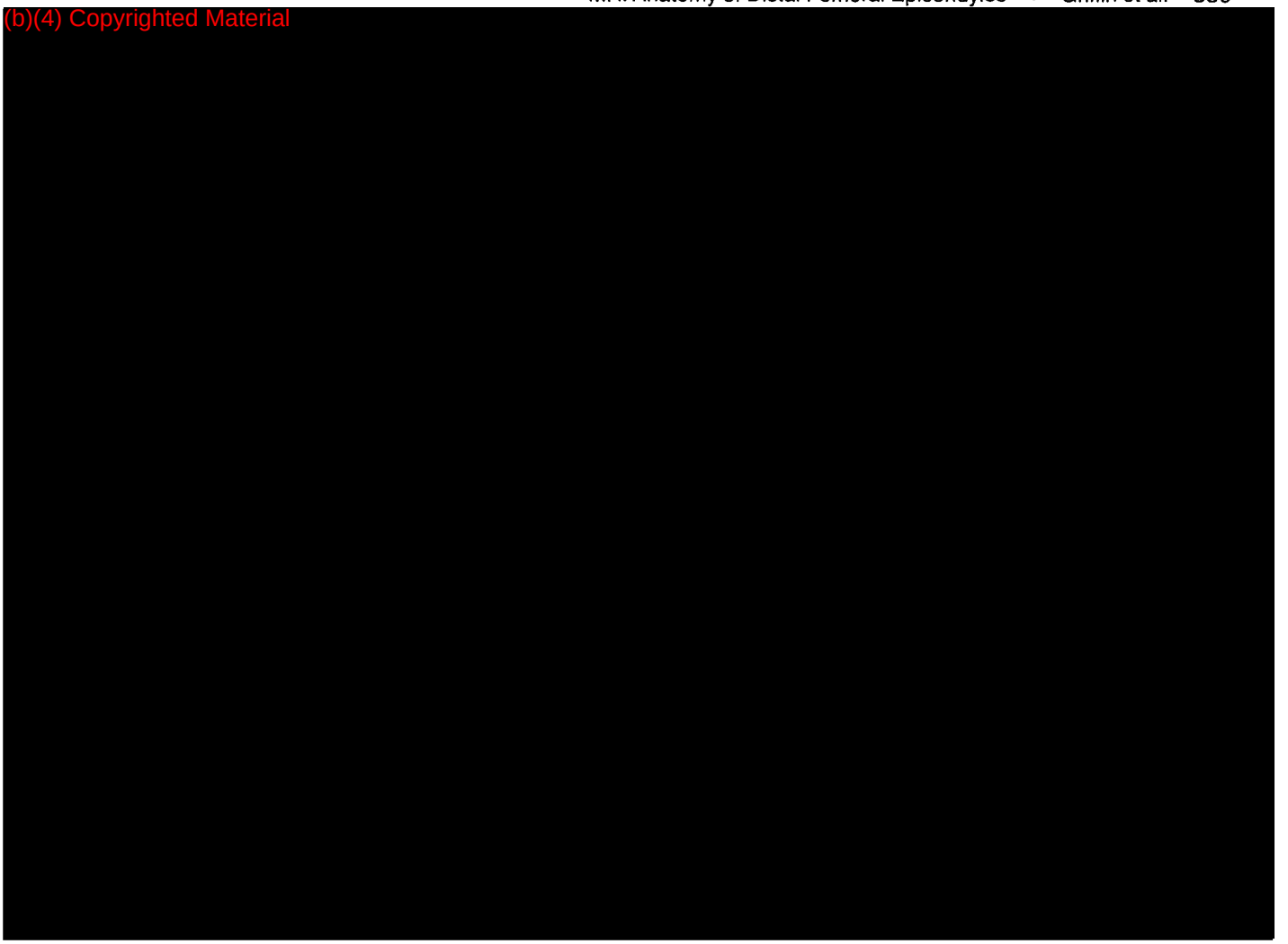
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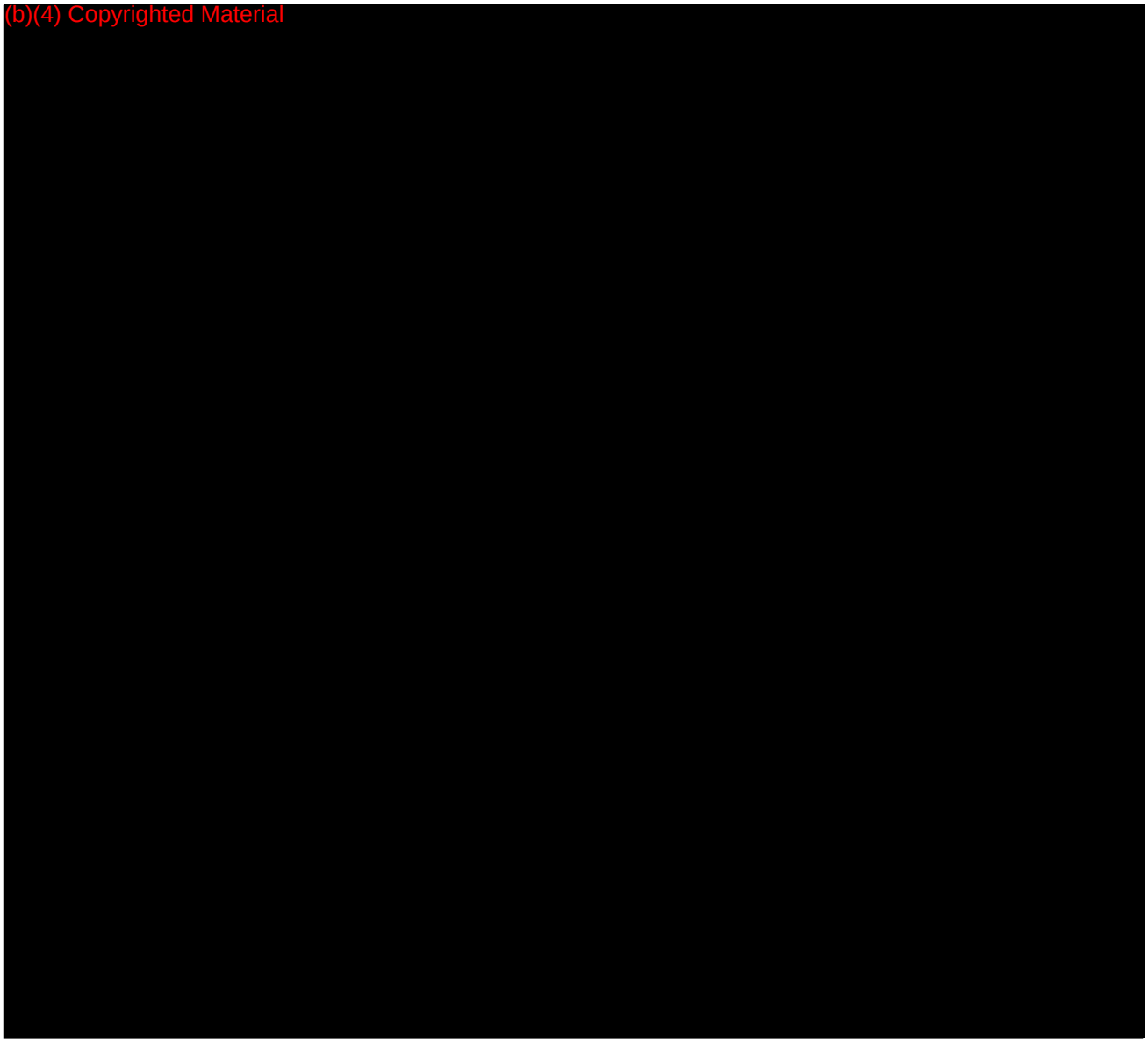
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CLINICAL ORTHOPAEDICS AND RELATED RESEARCH
Number 321, pp 168–172
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The Anteroposterior Axis for Femoral Rotational Alignment in Valgus Total Knee Arthroplasty

Leo A. Whiteside, MD; and Junichi Arima, MD

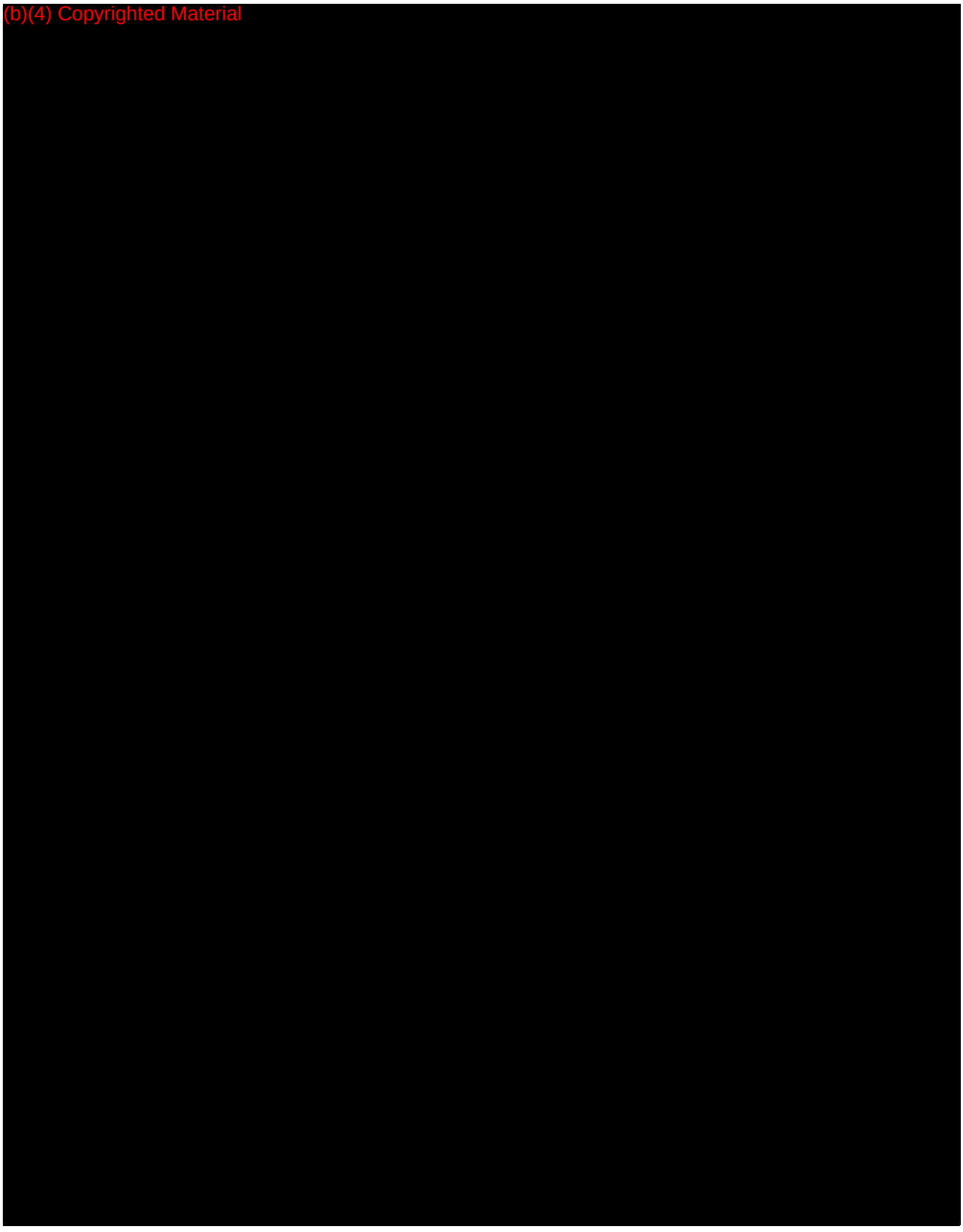
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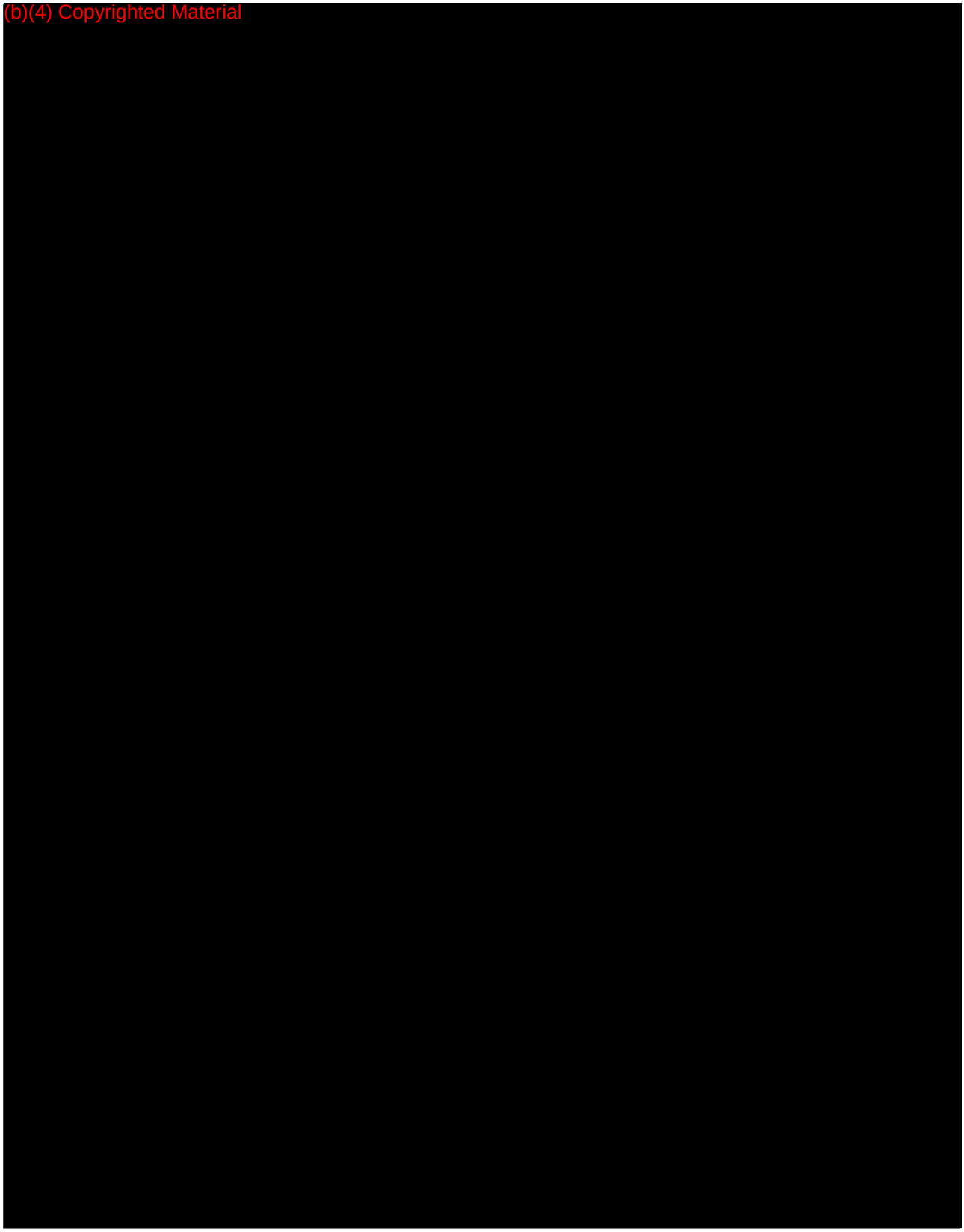
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THE JOURNAL OF BONE & JOINT SURGERY
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Influence of positioning of prosthesis in total knee replacement

PA Lotke and ML Ecker
J Bone Joint Surg Am. 1977;59:77-79.

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Influence of Positioning of Prosthesis in Total Knee Replacement

BY PAUL A. LOTKE, M.D.*, AND MALCOLM L. ECKER, M.D.*,
PHILADELPHIA, PENNSYLVANIA

From the Department of Orthopaedic Surgery, Hospital of the University of Pennsylvania, Philadelphia

ABSTRACT: **The early clinical results of geometric total knee arthroplasty were compared with the position of the prosthetic device by a roentgenographic score system. It was noted that there is a statistically significant positive correlation between a good clinical result and a well positioned prosthesis. In addition, it was appreciated that perfect positioning of the device was difficult to obtain. We believe that the long-term clinical results, wear resistance, and resistance to prosthetic failure depend on correct positioning of the devices.**

The designs of total knee replacements are based on biomechanical studies [1-5,7], and the objectives include the proper distribution of stress and a low rate of wear. Whether these goals are achieved depends on the correct application of the prosthesis in question. On reviewing our initial series of patients who had total knee arthroplasty with a geometric prosthesis, we were impressed by our difficulties in obtaining precise placement of the device. Therefore, we initiated a review to determine if there was a correlation between the positioning of the geometric total knee prosthesis and the clinical result.

Materials

All patients who had a geometric total knee arthroplasty between May 1972 and June 1974 were included in this series. A total of seventy-six prostheses were inserted in sixty-six patients. Forty-eight procedures were done for osteoarthritis (thirty-six in women and twelve in men); twenty-seven, for rheumatoid arthritis (nineteen in women and eight in men); and one, for ankylosing spondylitis (in a man). The average age of the osteoarthritic patients was 71.4 years and of the rheumatoid patients, 57.5 years. Surgery was performed by seven different surgeons and residents on the staff at the Hospital of the University of Pennsylvania. Fifty-nine of the prostheses were inserted by three of these physicians.

We personally performed follow-up evaluations one to three years after surgery. Seventy knees were available for review. Two patients had died of unrelated causes, and four were not available. This represents a follow-up of 92 per cent.

* Hospital of the University of Pennsylvania, 3400 Spruce Street, Philadelphia, Pennsylvania 19104.

Methods

The patients were evaluated preoperatively and post-

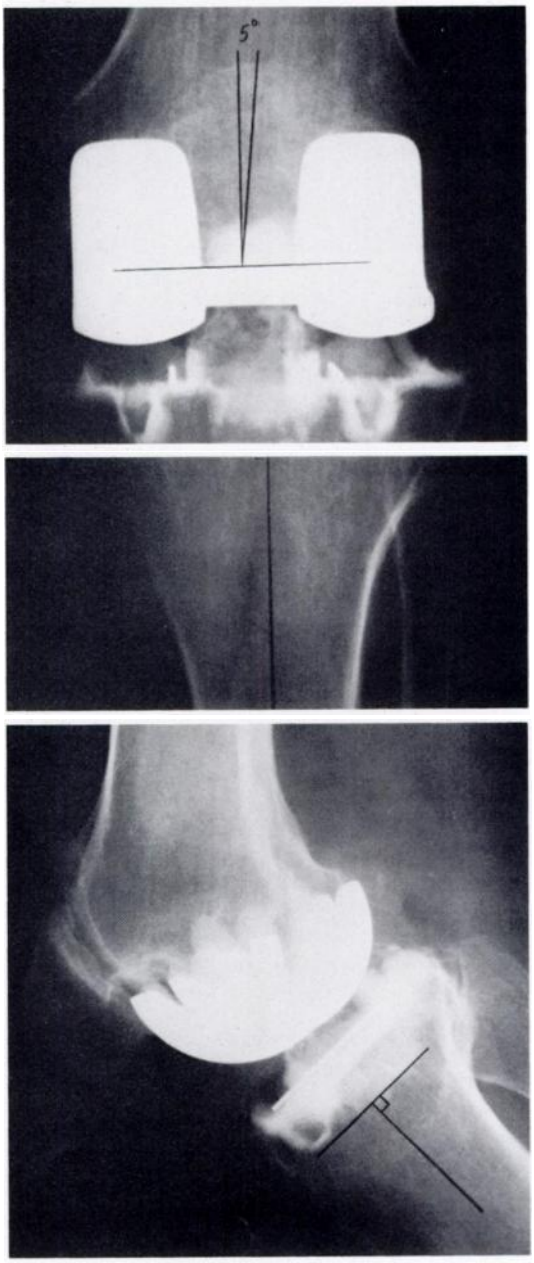


FIG. 1

Perfectly positioned total knee replacement.

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operatively and the findings were recorded on an evaluation form designed for computerized data retrieval. An index was developed that apportioned points for pain, function, and signs (Table I) from the information contained in the clinical evaluation form. A normal knee received 100 points.

The position of a prosthesis was evaluated by reviewing the initial postoperative roentgenogram and grading it on a previously developed scoring system (Table II). A perfectly positioned knee prosthesis (Figs. 1-A and 1-B) received 100 points, and the criteria for this rating were: over-all knee alignment in 3 to 7 degrees of valgus, the tibial component in a perfectly horizontal position in both planes, the femoral component in 4 to 6 degrees of valgus, and both femoral and tibial components centered in the midline of the joint. Deviations from these criteria resulted in lower scores.

TABLE I

KNEE EVALUATION INDEX*

I. Pain (possible 36 points)	
Pain at rest	
None	9
Mild	6
Moderate	3
Severe	0
Pain while walking	
None	27
Mild	18
Moderate	9
Severe	0
II. Function (possible 34 points)	
Use of aids	
None	18
Cane occasionally	15
Cane always	12
Crutches	9
Two canes or crutches	6
Walker	3
Wheelchair	0
Walking distance	
Unlimited	10
Minimum limitation	8
5 to 20 blocks	6
1 to 5 blocks	4
Indoors only	2
Bed to chair	0
Ability to rise from chair	
With ease	6
Minimum difficulty	4
Moderate difficulty	2
Unable to do so	0
III. Examination (possible 30 points)	
Flexion contracture	
0 degrees	9
0 to 2 degrees	8
3 to 5 degrees	7
6 to 10 degrees	6
11 to 15 degrees	5
16 to 20 degrees	4
21 to 25 degrees	3
26 to 30 degrees	2
31 to 45 degrees	1
More than 45 degrees	0
Flexion arch between 0 and 90 degrees multiplied by 0.1 (possible 9 points)	
Ligament stability — medial or lateral	
Normal	5
1 to 5 degrees	4
5 to 10 degrees	3
10 to 15 degrees	2
15 to 25 degrees	1
More than 25 degrees	0
Angular deformity — varus or valgus	
None	7
1 to 5 degrees	6
5 to 10 degrees	4
10 to 20 degrees	2
More than 20 degrees	0

* Normal knee = 100 points

TABLE II

ROENTGENOGRAPHIC INDEX*

I. Over-all alignment (possible 25 points)	
Neutral ± 2 degrees	20
Valgus	
3 to 7 degrees	25
8 to 12 degrees	15
13 to 20 degrees	5
More than 20 degrees	0
Varus	
3 to 7 degrees	15
8 to 12 degrees	5
13 degrees or more	0
II. Tibial component placement	
Anteroposterior view (possible 30 points)	
Horizontal	30
1 to 3 degrees varus or valgus	25
4 to 6 degrees varus or valgus	20
7 to 9 degrees varus or valgus	10
10 degrees or more varus or valgus	0
Lateral view (possible 10 points)	
Horizontal	10
0 to 3 degrees anterior/posterior tilt	8
4 to 6 degrees anterior/posterior tilt	4
7 to 9 degrees anterior/posterior tilt	2
10 degrees or more anterior/posterior tilt	0
Axial placement (possible 10 points)	
Central	10
Slightly offset	5
Markedly offset	0
III. Femoral component placement (possible 25 points)	
Horizontal	20
Valgus	
1 to 3 degrees	20
4 to 6 degrees	25
7 to 9 degrees	15
10 to 15 degrees	10
More than 15 degrees	0
Varus	
1 to 3 degrees	15
4 to 6 degrees	10
7 to 9 degrees	5
More than 10 degrees	0

* Perfect position = 100 points

Results

The clinical results showed that there was an over-all improvement when the average preoperative and postoperative scores of the patients were compared. The aver-

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age scores for patients with osteoarthritis were fifty points preoperatively and eighty-two points postoperatively. A similar rise was noted in the average scores of patients with rheumatoid arthritis, from forty-seven points preoperatively to seventy-nine points postoperatively. The greatest improvement in both groups was in the category of pain, for which a total of thirty-six possible points was allocated. The pain scores showed an improvement from an average of eight points preoperatively to twenty-nine points postoperatively.

The scores on the initial postoperative roentgenograms averaged 78.2 points. Only seven knees received a perfect score of 100 points. The average score for the first twenty-five knees in the series was seventy-five points, while the last twenty-five had an average score of 86.8 points.

The result indices were then compared with the roentgenographic scores. There were seventy pairings available for statistical analysis. Correlation coefficients and the paired t test both demonstrated a statistically significant correlation between good clinical results and good roentgenographic scores ($p < 0.05$). If the high half of the roentgenographic scores and their corresponding result indices were evaluated separately, twice as many patients had above-average clinical results as when the entire group was considered. This indicates that good placement of the prosthesis predisposes to a good clinical result.

Because this report concerns only the importance of prosthetic positioning, considerable information which is available on our computer forms is not being reported here. Our analysis of these data is similar to other series [6] and will be published later.

Discussion

The development of a point-score system for roentgenographic analysis allowed us to quantitate the positioning of a total knee replacement. Fewer than 10 per cent of our patients had a perfectly positioned prosthesis. Therefore, it is evident that correct positioning is very difficult to achieve.

The strong correlation between good positioning of the prosthesis and good early clinical results leads us to expect that poor alignment will result in abnormal stress and deterioration.

We have already noted five mechanical failures in our series. These presented as fractures of the medial tibial plateau. Because the series is relatively small, we cannot show statistically significant correlations of mechanical failure with the roentgenographic score. In four of the five instances of failure, the tibial components were positioned in varus.

Surgical experience in total knee replacement was also shown to be important in our series because the roentgenographic scores in our early cases were lower than those in the later ones. As more and more orthopaedic surgeons perform total knee-replacement arthroplasty, it will be increasingly important to stress the need for correct technique and the use of available guides to ensure the proper position of the devices. More effort should be expended on the development of better instruments to position the device's components, so that the operation will become a precise, well engineered procedure and will not depend on gross, subjective perceptions of alignment and mechanical relationships.

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POSTER NO. P193

Computer Assisted Total Knee Arthroplasty For Significant Tibial Deformities

Ritesh Shah, MD, Chicago, IL
Lalit Puri, MD, Glenview, IL
Gregory Strohmeyer, MD, Albuquerque, NM

The success of a primary total knee arthroplasty (TKA) is partly dependent on mechanical axis restoration and soft tissue balancing. In the presence of proximal tibial bony deficiencies, restoring proper implant and extremity alignment remains a significant challenge. Quantification of tibial plateau deformities has been performed by radiographic templating and manual intra-operative measurement. Alternatively, computer assisted total knee replacement (CAS TKR) may allow tibial plateau deformities to be quantified prior to performing tibial osteotomies. In this prospective study, we describe the use of computer navigation to quantify the amount of bone loss on the medial or lateral tibial plateau and assess the need for and use of metallic tibial augmentation. A total of 439 consecutive primary CAS TKR were performed by one surgeon. Navigation instruments quantified the tibial deformities by inputting the lowest point on the deformed tibial plateau and the mid-point on the non-deformed tibial plateau. Inclusion criteria were patients undergoing CAS TKR in whom the measured difference between the medial tibial plateau and lateral tibial plateau exceeded 13 mm and the tibial deformity involved greater than one-third of the tibial plateau. All tibial deformities greater than 13 mm utilized tibial augmentation. We noted the navigated measured bony defect size, size of tibial wedges, prostheses used and polyethylene size. Radiographs were reviewed to measure the joint line restoration and final mechanical limb alignment. Twelve knees (2.7%) had tibial deformities greater than 13 millimeters and required tibial plateau metallic wedge augmentation. The mean measured tibial plateau discrepancy was 18 mm; six knees required a 5 mm tibial wedge and six knees required a 10 mm tibial wedge. The mean polyethylene size used was 11 mm. Mean overall post-operative mechanical alignment was 0.08 degrees of valgus. Mean joint line restoration was 2.8 mm. CAS TKR is helpful in accurately measuring severe tibial deformities, predicting tibial augment thickness and restoring the mechanical alignment and joint line.

POSTER NO. P194

Inflammatory Response of Human Articular Chondrocytes to Wear Debris

Lige Kaplan, MD, Royal Oak, MI
Carly Gratopp
Erin Ann Baker, MS, Royal Oak, MI
Kevin Baker, MS, Royal Oak, MI

Unicompartmental knee arthroplasty (UKA) systems are commonly revised due to progression of arthritis characterized by cartilage degeneration. Retrieval studies have revealed significant mechanical damage to UKA components capable of generating particulare debris. The goal of this study is to investigate the potential role of implant wear in the biologic destruction of cartilage through in vitro analyses. Normal human articular chondrocytes (nHAC) from the knee were cultured on top of cross-linked ultra high molecular weight polyethylene (UHMWPE), cobalt-chromium-molybdenum (CoCrMo) or Ti6Al4V particles (0.1 or 1.0 mg/mL) in 24-well culture plates. Cell morphology was monitored at 24-hour intervals by phase contrast microscopy. Production of TNF-a, IL-1b, IL-10 was assayed by ELISA at one, three, five and seven days. Viability was compared between the materials and doses after seven days by mean transit [illegible] assay. At four hours, cells entered a phagocytotic phase with active uptake of particles within cell membranes. Cell detachment was apparent in CoCrMo and UHMWPE-treated wells. Expression of inflammatory cytokines was dose, time and material-dependent. IL-10 was expressed at the highest levels, followed by IL-1b and TNF-alpha. Cell viability was both material and dose dependent, with the largest reductions in viability coming from CoCrMo-treated wells (73.6%), followed by UHMWPE (43.7%) and Ti6Al4V (4.4%). Material and dose-dependent changes in cell morphology, cytokine expression and cell viability suggests that wear debris may have the potential to induce degenerative changes in cartilage adjacent to UKA components.

POSTER NO. P195

The Financial Impact Of Our Innovative Joint Replacement Program In Our Regional Medical Center

Jon R Cook, PT, Cottonwood, AZ
Jack W Wylie, MD, Cottonwood, AZ
Paul Prefontaine, PT

A product line profitability analysis (PLPA) which is generated from the Medicare cost report is a method used to evaluate the financial solvency of hospital joint replacement programs (JRP). However, cost reports include a large amount of indirect cost which can overestimate the cost of treating this population. This discrepancy may underestimate the financial contribution JRPs make to their institutions. We compared PLPA to direct cost and total reimbursement for JRP cases in our regional medical center. Fifty-three cases over a period of 10 months were randomly selected for analysis of the direct cost of performing their joint replacement surgery. This included an itemized tracking of cost including pre-op education, surgical procedure including implant, social services, nursing, lab, radiology, rehab, pharmacy and dietary, among others. We then compared our findings to the total reimbursement and the PLPA for the same cohort. The average cost was $8,759 and the average reimbursement was $18,485 giving average revenue of $9,727 per case. The PLPA calculated an average cost of $18,141 and $18,509 average reimbursement leading to $369 average revenue per case. Due to a large indirect cost which is greater than the direct cost, the PLPA calculated a significantly higher cost per case, which led to lower revenue. Such an underestimation of revenue can lead institutions to make adverse decisions on a JRP's solvency or program development. Since indirect costs are constant, a decision to eliminate a JRP based solely on PLPA solvency would only further indebt the hospital.

POSTER NO. P196

Accuracy Of Implant Placement Using Customized Patient Instrumentation

Hideki Mizuuchi, MD, La Jolla, CA
Shantanu Patil, MD, La Jolla, CA
Darryl D D'Lima, MD, La Jolla, CA
William Bugbee, MD, La Jolla, CA

Alignment and positioning of implants is important in total knee arthroplasty (TKA). Customized patient instrumentation (CPI) is an innovation that combines preoperative planning with customized cutting jigs. We compared the postoperative implant alignment of patients undergoing surgery with CPI to standard TKA instrumentation. Twenty-five consecutive TKA using CPI were analyzed. Preoperative CT scans of the patients' lower extremity were segmented using MIMICS. Limb alignment and mechanical axes were computed. Based on the preoperative planning protocol, virtual implantation of implant CAD models was done using Rhino.

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Postoperative coronal alignment and implant positioning were measured. Using 3D-image-matching software, relative positions of the femoral and tibial implant were obtained from radiographs. Lowest contact point between femur and tibial inserts was calculated, imported into Rhino and compared to virtual surgical placement. Twenty-five TKAs implanted using standard instrumentation were analyzed. For CPI, difference in alignment from the preoperative plan was calculated. For the standard TKA group, targeted alignment was 90° in both planes for the femur and 90° coronal for the tibia. In the CPI group, mean absolute difference between planned and actual femoral placement was 0.7° (SD 0.5) in the coronal plane and 1.2° (SD 0.9) in the sagittal plane. For the traditional instrumentation group, difference from ideal placement for the femur was 1.5° (SD 1.6) in the coronal and 2.3° (SD 1.3) in the sagittal plane. This was statistically significant at P< 0.001. In the CPI group, mean difference for the tibia was 0.9° (SD 0.6) in the coronal plane, as compared to 1.8° (SD 1.6) in the standard instrumentation group. (NS) CPI achieved accurate implant positioning that was superior to traditional total knee instrumentation.

POSTER NO. P197

Patellofemoral Kinematics for Obese, Overweight and Normal Weight TKA Subjects

Matthew Anderle, Parker, CO
Sumesh M Zingde, Knoxville, TN
Richard D Komistek, PhD, Knoxville, TN
John P Mueller, PhD, Knoxville, TN
Duarte Y Ho, BS
Douglas A Dennis, MD, Denver, CO

The objective of this study was to compare in vivo 2D patellofemoral kinematics in total knee arthroplasty (TKA) subjects by body mass index (BMI). A total of 266 TKA subjects were analyzed using fluoroscopy and a 2D measurement software package to determine patellofemoral angle (PA) relative to the femur and the normalized patellofemoral contact position (PC) from the distal end of the patella during a deep knee bend from full extension to maximum flexion. Each subject was classified as obese, overweight or normal weight using a standard BMI scale. Implant type analysis was also conducted on the mobile bearing, fixed bearing, posterior stabilized, bi-cruciate stabilized, cruciate retaining, anterior cruciate retaining and medial pivot groups. From full extension to maximum flexion the obese (n=82), overweight (n=123) and normal weight (n=61) groups averaged 74.0°, 75.3° and 80.4° of patellofemoral rotation. The obese group's PA was significantly higher at full extension than normal weight group (3.2° vs 1.1°, p=0.0344). A similar trend was seen in every implant type group analyzed. From full extension to maximum flexion, the obese, overweight and normal weight groups experienced 0.34, 0.34 and 0.32 times patella length of PC translation. When analyzed by implant type, only the mobile bearing group showed a significant difference (normal weight compared to overweight at 60°, p=0.0409) at any contact point increment. All other implant type groups were similar at each increment, across the three BMI categories, within the same implant group. It can be concluded that BMI does play a factor in patellofemoral kinematics, particularly in patellofemoral angle.

Patient and Surgical Factors Associated with Primary TKA Outcomes in the United States

Robert S Namba, MD, Corona Del Mar, CA
Maria Carolina Secorun Inacio, MS, San Diego, CA
Liz Paxton, MA, San Diego, CA
Christopher F Ake, PhD, Corona Del Mar, CA
Monti Khatod, MD, Santa Monica, CA
Eric J Yue, MD, Carmichael, CA

Factors associated with total knee arthroplasty (TKA) outcomes are unclear. TKA patient demographics, surgical information, surgeon and hospital volume, implant characteristics and subsequent revision procedures were recorded in a total joint replacement registry (TJRR). Descriptive, survival and multivariate analyses are presented. A total of 47,429 primary TKA cases were performed between 2001 and 2009. The patients were predominantly female (63%) with 38% <65 years old. The revision rate was 1.9% (N=882) including 0.8% for septic revisions (N=366). Cumulative survival rate was 96.4% at six years. Reasons for revision included: infections 42%, instability 19% and aseptic loosening 12%. Cox regression analysis revealed the following risk factors for aseptic revision: younger age (P<0.0001), African American race (P<0.0001), ASA classification >=3 (P=0.047), diabetes (P=0.048) and unresurfaced patella (P=0.028). Bilateral procedures were protective (P=0.001). Surgeon and hospital case volume, body mass index, gender, operative time and surgical approach were not significant risk factors when adjusting for all other variables in the model. Patient factors associated with increased risk of aseptic revision include younger age, African American race, higher ASA classification and diabetes. Surgical factors associated with revision include unresurfaced patellae.

POSTER NO. P199

Prosthetic Joint Infection caused by Gram Negative Organisms

Javad Parvizi, MD, Philadelphia, PA
Catherine Julia Fedorka, MD, Philadelphia, PA
Mr Benjamin Zmistowski, Philadelphia, PA
Mr Eoin C Sheehan, Tullamore, Ireland
Peter F Sharkey, MD, Media, PA
James J Purtill, MD, Philadelphia, PA

Periprosthetic joint infection (PJI) is a serious complication following total joint arthroplasty (TJA). Traditionally PJI due to gram-negative (GN) organisms are considered more difficult to manage, however little literature exists with regard to outcome of PJI caused by GN organisms. This comparative study was designed to evaluate whether the outcome of PJI caused by GN organisms differed from that caused by gram-positive organisms. The joint infection database at our institution provided 278 patients with 283 PJI receiving surgical treatment between 1999 and 2007. Average follow up was 46.2 months (range: 12-175). Forty patients (15 hips and 25 knees) had GN PJI. The GN group was then compared to 112 methicillin sensitive gram-positive (MSGP) PJI and 131 methicillin resistant gram-positive (MRGP) PJI. Known predictors of infection were compared between GN and gram-positive PJI. A significantly greater proportion of GN (30%) were acute (<6 weeks) compared to MSGP (18%); no difference was observed with MRGP. A single debridement and retention of prosthesis was successful in 58.8% (10/17) of GN compared to 34.3% (13/38) of MSGP and 49% (24/49) of MRGP PJI. However, reimplantation was attempted in only 58.7% (17/29) of GN compared to 80.4% (74/92) of MSGP and 73.1% (76/104) of MRGP. Of those reimplanted, two-stage revision was successful

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knee score mean was 82 (range, 37 to 100). Twenty-nine knees (13%) had been revised. One knee was revised for progression of pigmented villonodular synovitis (PVNS). Thirteen knees failed with tibial components subsidence/loosening, which commonly began as progressive cystic degeneration beneath the tibial component. Six knees were revised elsewhere. Five-year survivorship was 97%; survivorship at 10 years was 78%. At mean 9.5 year follow up, this UKA demonstrated 78% survivorship. The dominant mode of failure was subsidence/loosening of the all-polyethylene fixed-bearing tibial component, with a troubling number of this failure mode occurring between seven and 10 years. We will continue to follow this cohort closely. The principles of small incision, minimal quadriceps dissection, local injection and early mobilization have been incorporated into all current UKA patients.

PAPER NO. 298

Custom Guides for Primary Total Knee Arthroplasty

Adolph V Lombardi Jr, MD, New Albany, OH
Keith R Berend, MD, New Albany, OH
Roger H Emerson, Jr MD, Dallas, TX
Michael D Skeels, DO, New York, NY
Joanne B Adams, BFA, CMI, New Albany, OH
Bethany C Gulick, RT

Efforts to enhance technique in primary total knee arthroplasty (TKA) while avoiding negative aspects of navigation have fueled development of patient-specific guides generated from MRI or CT. We review our experience to date with TKA performed using patient-specific guides and compare the accuracy to standard technique via both radiographic and cadaveric studies. Two surgeons performed bilateral TKA on nine cadavers, using standard instrumentation on one side and custom guides contralaterally. TKA were evaluated postoperatively with CT for accuracy of femoral and tibial resection and femoral rotation. To date, 316 patients (364 knees) have undergone primary TKA at one center using patient-specific guides. From this series, 91 custom-guided TKA were matched to 91 contemporaneous TKA performed with standard instrumentation. Postoperative standard AP radiographs were evaluated via calibrated picture archiving and communication system (PACS) by independent observer for femorotibial, femoral component and tibial component alignment. Long alignment radiographs were evaluated for 71 custom-guided TKA. Outliers were defined as >3° from goal. Accuracy for standard versus custom-guided cadaveric TKA femoral alignment averaged 2.1°±1.8° versus 1.5°±1.4°, for rotation averaged 1.6°±1.1° versus 1.0°±0.6° and for tibial alignment averaged 1.3°±0.8° versus 1.5°±0.7°, which are not significantly different with numbers available. There were four outliers overall in the standard group versus one using custom-guides (NS). In the radiographic comparison, femorotibial, femoral component and tibial component alignment were all significantly more accurate using custom guides. Furthermore, there were more outliers in the standard group (6.6%; 18/273) than the custom-guided group (1.5%; 4/273; p=0.002). Review of long alignment series revealed restoration of mechanical axis to within 3° in all cases. Disposable patient-specific custom guides improve accuracy of alignment and component rotation in primary TKA. They provide ease and speed of use, efficiency in implant sizing and inventory, without cumbersome equipment or violation of the intramedullary canal, and are compatible with minimally invasive techniques.

Inappropriate Use of Magnetic Resonance Imaging of the Knee by Referring Physicians

Harpal Singh Khanuja, MD, Cockeysville, MD
Maria S Goddard, MD, Winston Salem, NC
Simon Mears, MD, Baltimore, MD
Lynne C Jones, PhD, Baltimore, MD

Currently, healthcare accounts for 15% of the gross domestic product in the United States. Identifying areas of reducing healthcare expenditures is essential. Patients with knee pain referred to orthopedists may already have magnetic resonance imaging (MRI) studies ordered by their primary provider. The purpose of this study was to investigate the appropriateness of knee MRI studies ordered by referring physicians. This prospective study evaluated 108 consecutive patients (27 men, 80 women and one unrecorded) with a new onset of knee pain presenting to the Orthopaedic Clinic, between February and April 2009. Questionnaires were completed by the orthopaedic surgeon at the time of each encounter. Questions included whether patients presented with MRI studies, if there was a need for additional imaging and whether an MRI was necessary to obtain a diagnosis. Sixty-six patients (61%) were referred by their primary care physicians, 25 patients (23%) by other physicians, 10 patients (9%) were self-referred. The referring physician was unknown for seven patients. Thirty-three patients (31%) presented with MRIs studies, 18 (55%) of which were considered unnecessary, as the diagnosis was possible with history, physical examination and radiographs alone. Two of six MRI studies ordered by referring orthopeic physicians were not necessary. Of the 75 patients (69%) who presented without an MRI study, only four required further MRI evaluation. The most common final diagnosis for this cohort was osteoarthritis in 41 patients (38%), followed by patellofemoral syndrome in 14 patients (13%) and meniscal tears in eight patients (7%). Although MRIs are useful in many diagnoses of knee pathology, they are an expensive screening tool. In this cohort, MRI was only warranted in 20% of cases, and 55% of MRIs ordered by referring physicians were unnecessary. It is important that clinicians be educated on the indications for MRI, and universal standards be developed.

PAPER NO. 300

Do Current High Flexion Posterior Stabilized TKA Designs Increase Knee Flexion? - A Meta Analysis

Takanobu Sumino, MD, Boston, MA
Harry E Rubash, MD, Boston, MA
Kartik Varadarajan, MS, Boston, MA
Young-Min Kwon, MD, PhD, Boston, MA
Guoan Li, PhD, Boston, MA

It remains debatable whether the design changes in current high-flexion (H-F) total knee arthroplasty (TKA) facilitate increased postoperative knee flexion, with conflicting results being reported by individual studies. Therefore, the goal of this work was to utilize a meta-analysis approach to integrate available published data from various studies into a common framework. In particular we examined whether current posterior stabilized (PS) H-F TKA designs provide increased range of knee motion. We conducted a systematic review of literature published between 1966 and 2010 through Medline and EMBASE. The inclusion criteria were: primary TKA study, follow up duration greater than one year, use of PS type prosthesis and reporting of maximal pre- and postoperative knee flexions along with standard deviations. We estimated the weighted mean differences between preoperative and postoperative flexions via random effect modeling.

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The Journal of Arthroplasty Vol. 16 No. 5 2001

The Effect of Surgeon Experience on Component Positioning in 673 Press Fit Condylar Posterior Cruciate–Sacrificing Total Knee Arthroplasties

J. Mahaluxmivala, MS (Orth), MSc (Orth), M. J. K. Bankes, BSc, FRCS (Orth), P. Nicolai, FRCS, C. H. Aldam, FRCS, and P. W. Allen, BSc, FRCS

Abstract: Component angles of 673 Press Fit Condylar (PFC) total knee arthroplasties were measured from standard short-leg radiographs. The femoral and tibial resections were performed with intramedullary and extramedullary instrumentation. The mean coronal tibial component angle was 88.59° (SD, 2.28°; range, 78–98°), with 17.1% having values <87° and 1.9% having values >93°. The mean coronal femoral component angle was 97.43° (SD, 3.44°; range, 84–115°), with 9.1% having values <94° and 13.1% having values >100°. An ideal tibiofemoral angle of 4° to 10° of valgus was achieved in 75.3% of patients, being <4° in 18.6% and >10° in 6.1%. Alignment was not significantly different between consultant and trainee surgeons. Although varus positioning of the tibial component was the commonest error, the wide range of femoral component angles signifies problems with standard intramedullary femoral guides. **Key words:** total knee arthroplasty, alignment, intramedullary, extramedullary, femoral, tibial, surgeon grade.

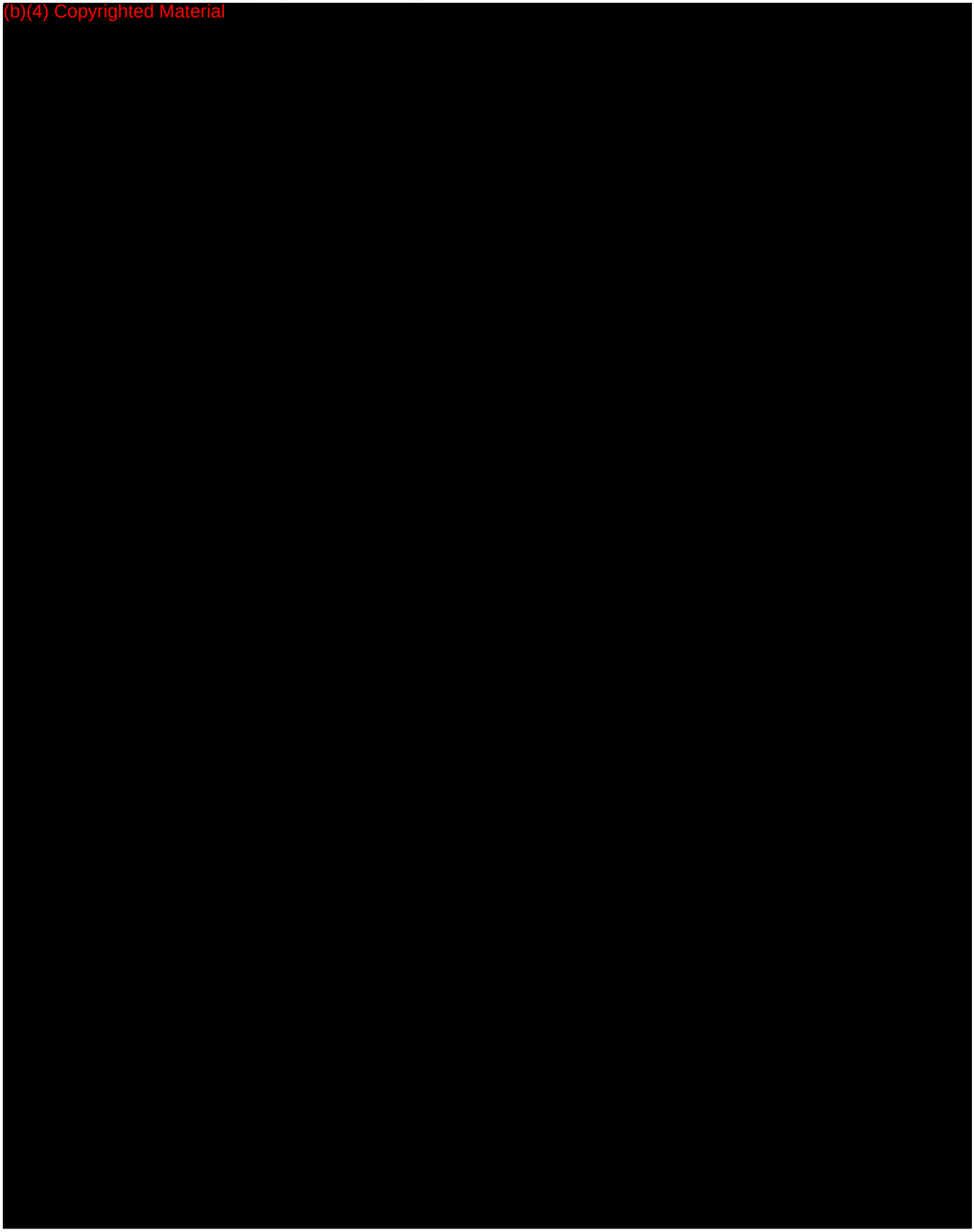
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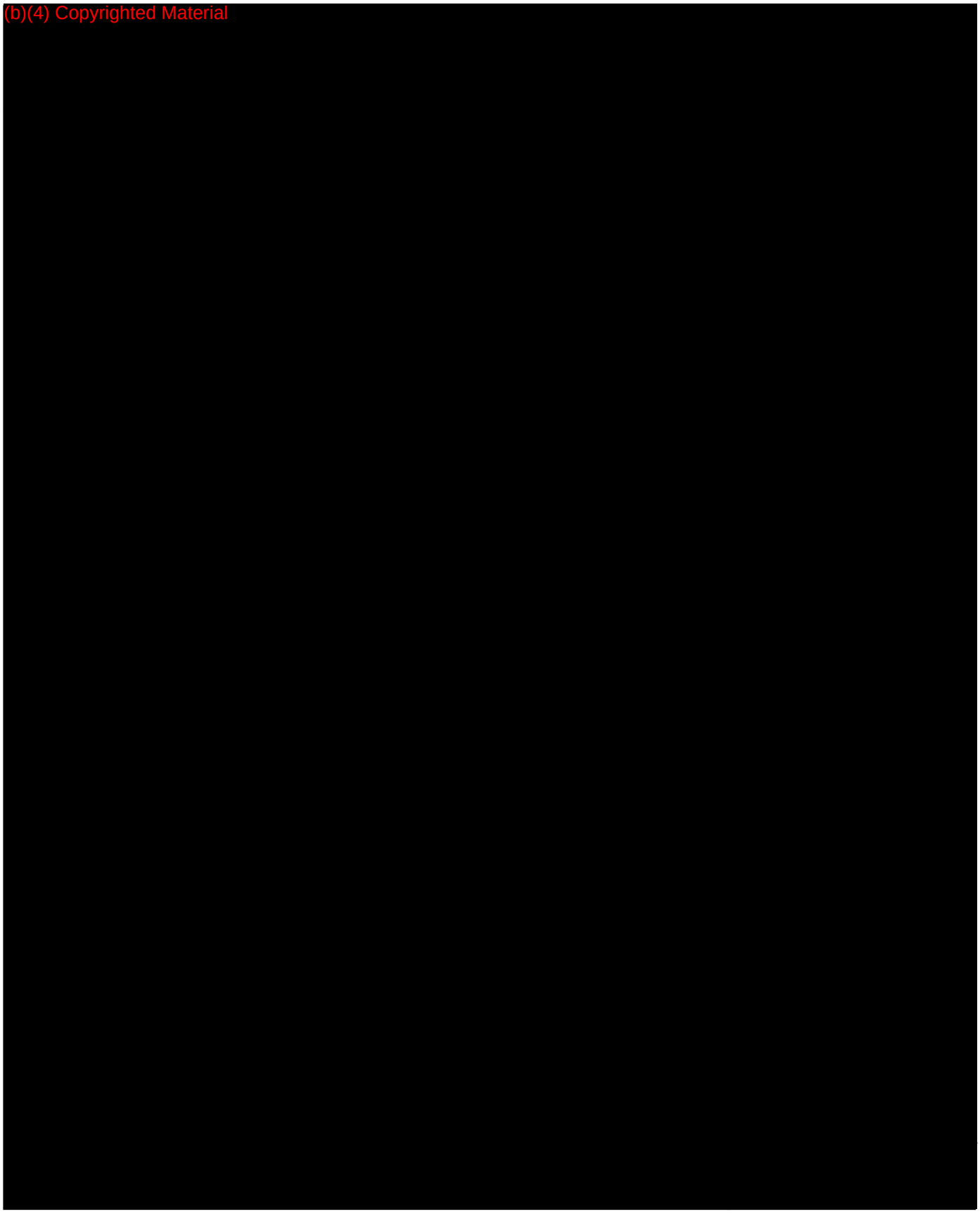
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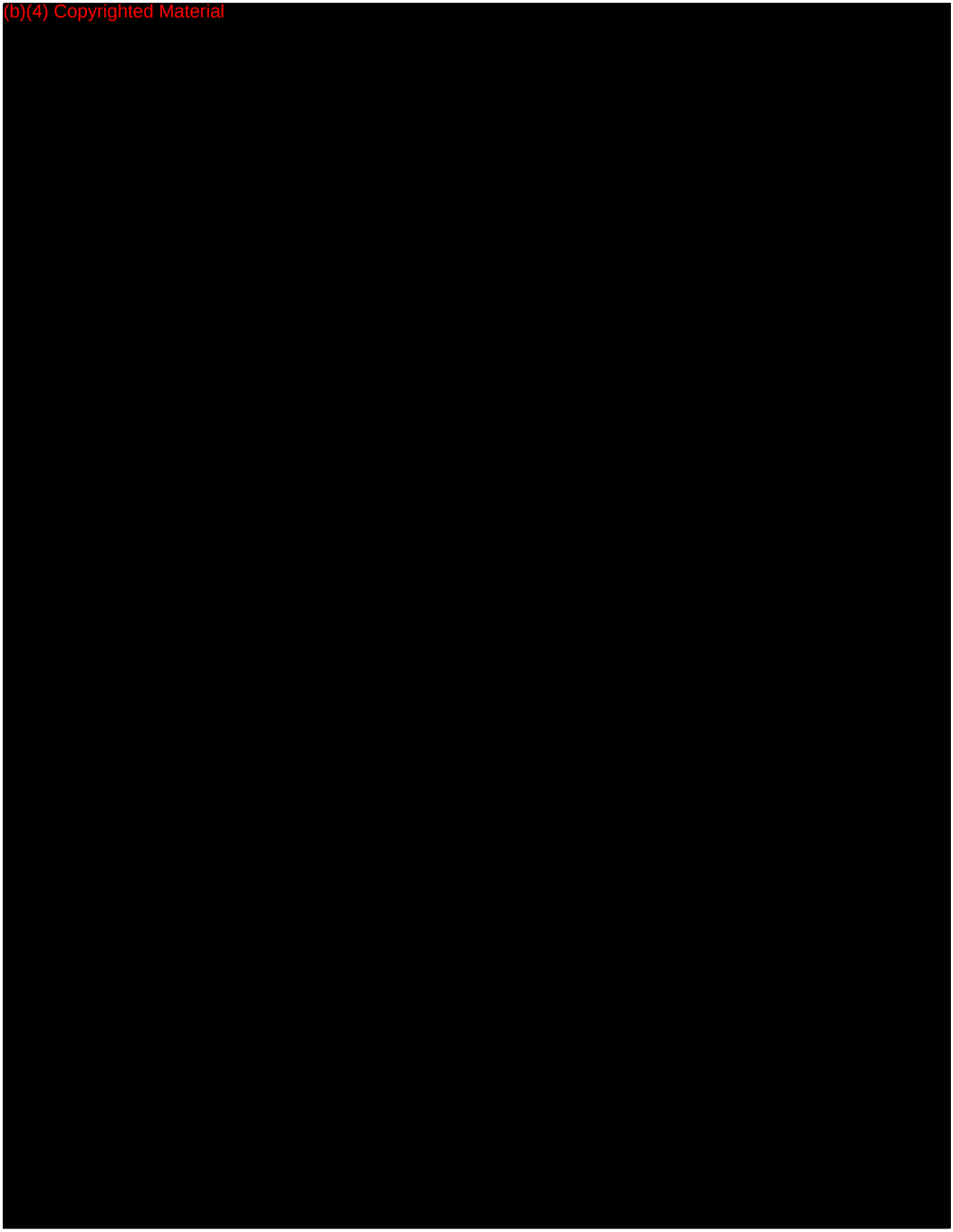
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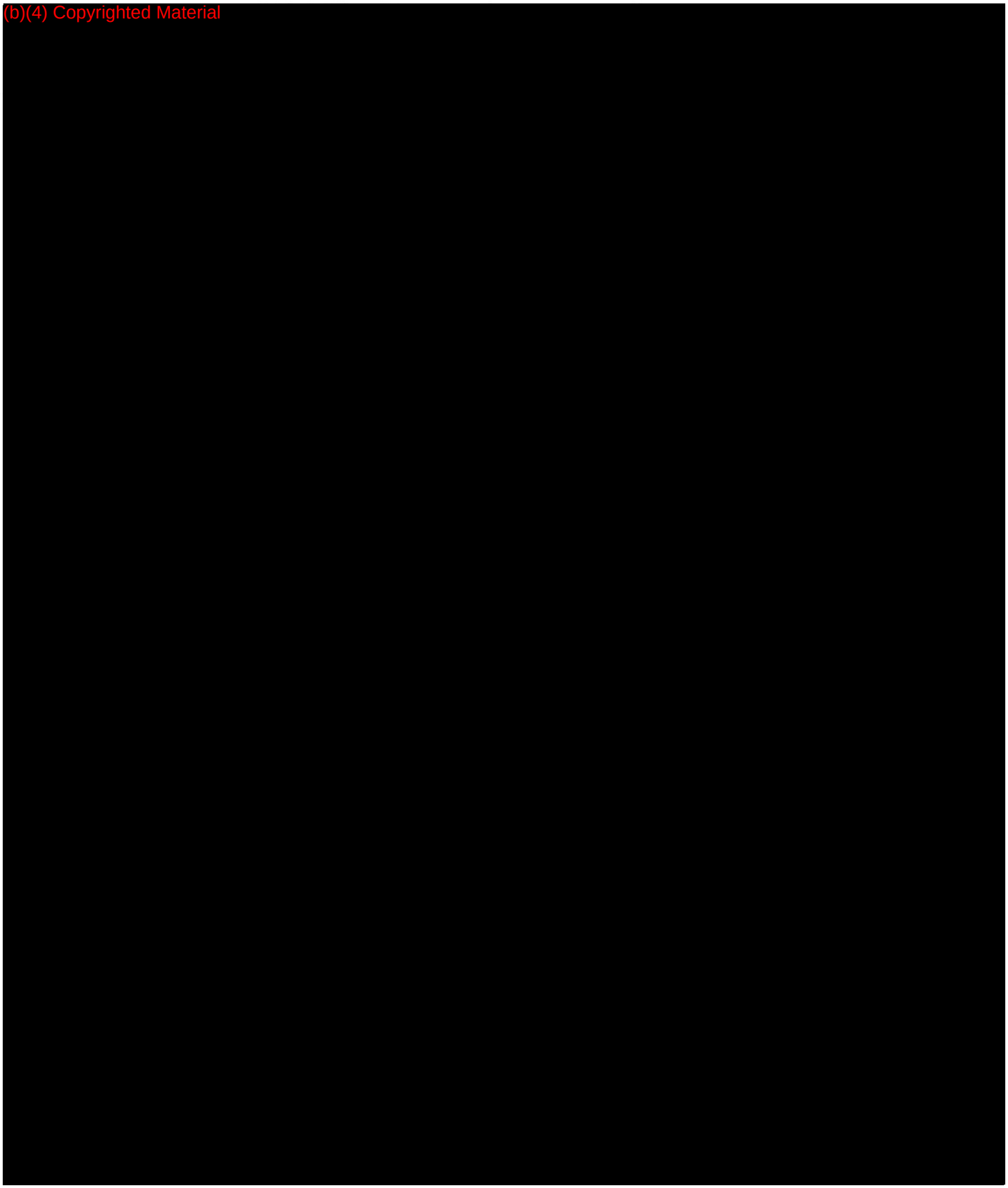
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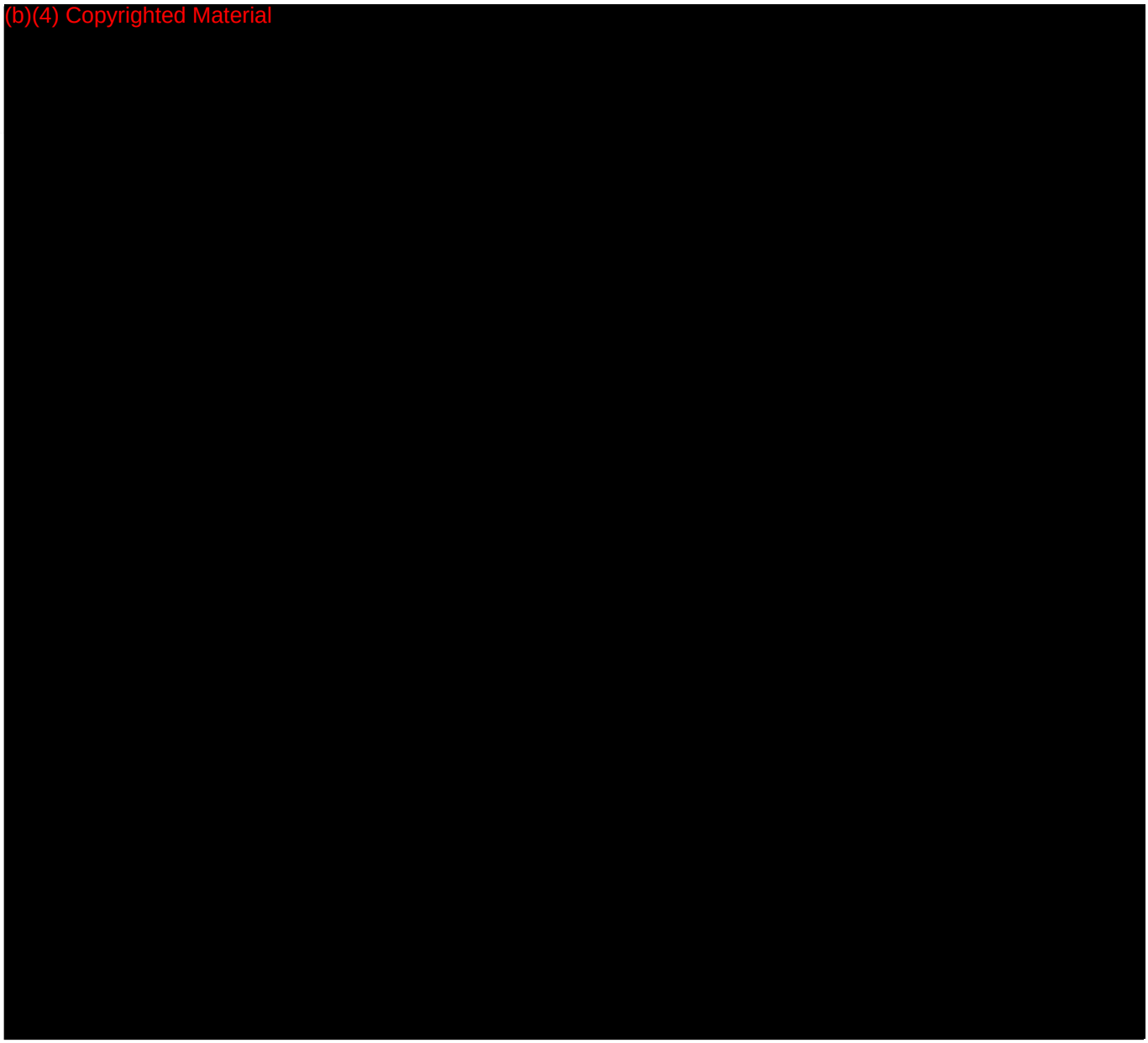
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A Prospective, Randomized Study of Computer-Assisted and Conventional Total Knee Arthroplasty. Three-Dimensional Evaluation of Implant Alignment and Rotation

Georg Matziolis, Doerte Krocker, Ulrike Weiss, Stephan Tohtz and Carsten Perka
J Bone Joint Surg Am. 2007;89:236-243. doi:10.2106/JBJS.F.00386

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A Prospective, Randomized Study of Computer-Assisted and Conventional Total Knee Arthroplasty

Three-Dimensional Evaluation of Implant Alignment and Rotation

By Georg Matziolis, Dr med, Doerte Krocker, Dr med, Ulrike Weiss, Stephan Tohtz, Dr med, and Carsten Perka, Prof Dr med

Investigation performed at the Center for Musculoskeletal Surgery, Charité-University Medicine, Berlin, Germany

Background: Despite the use of modern instruments in total knee arthroplasty, component malalignment remains a problem. Whether a computer-assisted implantation technique can improve the accuracy of the spatial positioning of an implant is a matter of debate. The objective of this study was to determine whether computer-assisted total knee arthroplasty is superior to the conventional surgical method with regard to the precision of implant positioning.

Methods: The spatial positioning of the implant in sixty total knee arthroplasties (thirty-two imageless computer-assisted and twenty-eight conventional implantations) was determined three-dimensionally with use of computed tomographic measurement, which allowed derotation and full extension of the knee in order to avoid projection-related imaging errors.

Results: The overall mechanical axis showed a range of between 4.8° of valgus and 6.6° of varus alignment in the frontal plane for conventionally implanted arthroplasty components compared with a significantly smaller range of between 2.9° of valgus and 3.1° of varus alignment for computer-assisted implantations ($p = 0.004$). In relation to the tibial implant, the mean deviation (and standard deviation) from the mechanical axis was 2.0° ± 1.7° for the conventional surgical method and 1.4° ± 0.9° for the navigated implantation. The rotational deviation from the referenced axis of the femoral component was between 3.3° of internal rotation and 5.0° of external rotation for the conventional implantation method, with a mean deviation of 0.1° ± 2.2°. Femoral components implanted with computer assistance showed a deviation of between 4.7° of internal rotation and 2.2° of external rotation, with a mean deviation of 0.3° ± 1.4°.

Conclusions: In this study, with our technique of filtering out projection-related imaging errors, computer-assisted implantation of total knee replacements improved the frontal and sagittal alignment of the femoral component but not of the tibial component. We found that the rotational alignment of the component was not improved through navigation by solely referencing to the epicondylar axis for the femur and the tuberosity for the tibia.

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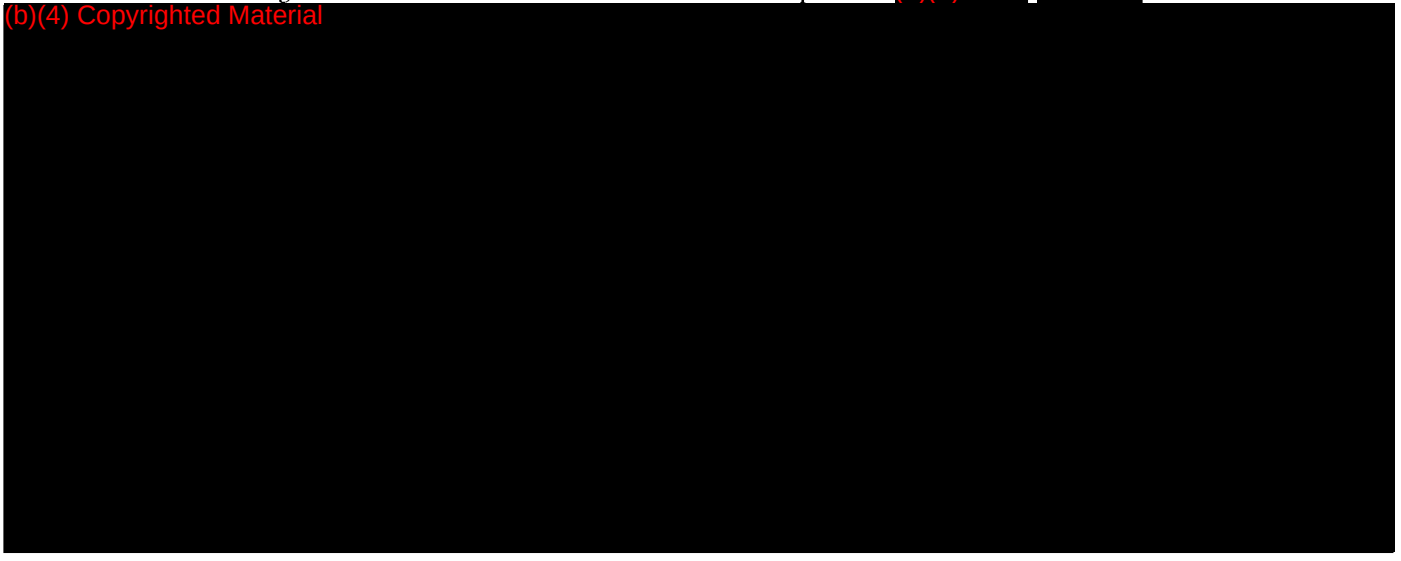
Influence of Intramedullary Versus Extramedullary Alignment Guides on Final Total Knee Arthroplasty Component Position

A Radiographic Analysis

Antonio Maestro, MD,* Steven F. Harwin, MD, FACS,†
Manuel G. Sandoval, MD,‡ Daniel H. Vaquero, MD,‡ and Antonio Murcia, MD*

Abstract: A prospective study of 116 consecutive Kinemax cemented posterior cruciate ligament-retaining total knee arthroplasties was carried out. Similar surgical technique was used with a single variable: 61 were implanted using intramedullary guides on the tibia and 55 were implanted using extramedullary guides on the tibia. A radiographic study was performed after at least 1 year of follow-up to evaluate postoperative component position and compare the difference in the accuracy of positioning of the femoral and tibial components. Radiographic analysis showed that satisfactory position was achieved using both types of instrumentation. No statistically significant difference was observed in either the coronal or sagittal plane of the femoral component and the sagittal plane positioning of the tibial component. However, the coronal plane positioning of the tibial component revealed a statistically significant difference ($P < .01$), with intramedullary guides being superior to extramedullary guides. Also observed, was that using either technique, patients with less accurate postoperative positioning tended to be obese, with wide intramedullary canals. Patients with significant extraarticular deformities, marked bowing, and those with prior surgery or fractures may not be suitable for intramedullary guides, and they may require the use of extramedullary guides and intraoperative radiographic control. The ideal indication for the use of intramedullary instrumentation is in the patient who is not obese, with no extraarticular deformity, and with a well-defined, but not excessively wide, tibial medullary canal. Since tibial component malalignment in general, and coronal plane malalignment in particular, may adversely affect the long-term survival of total knee arthroplasties, the use of intramedullary alignment instrumentation is recommended when possible. (b)(4) [redacted]

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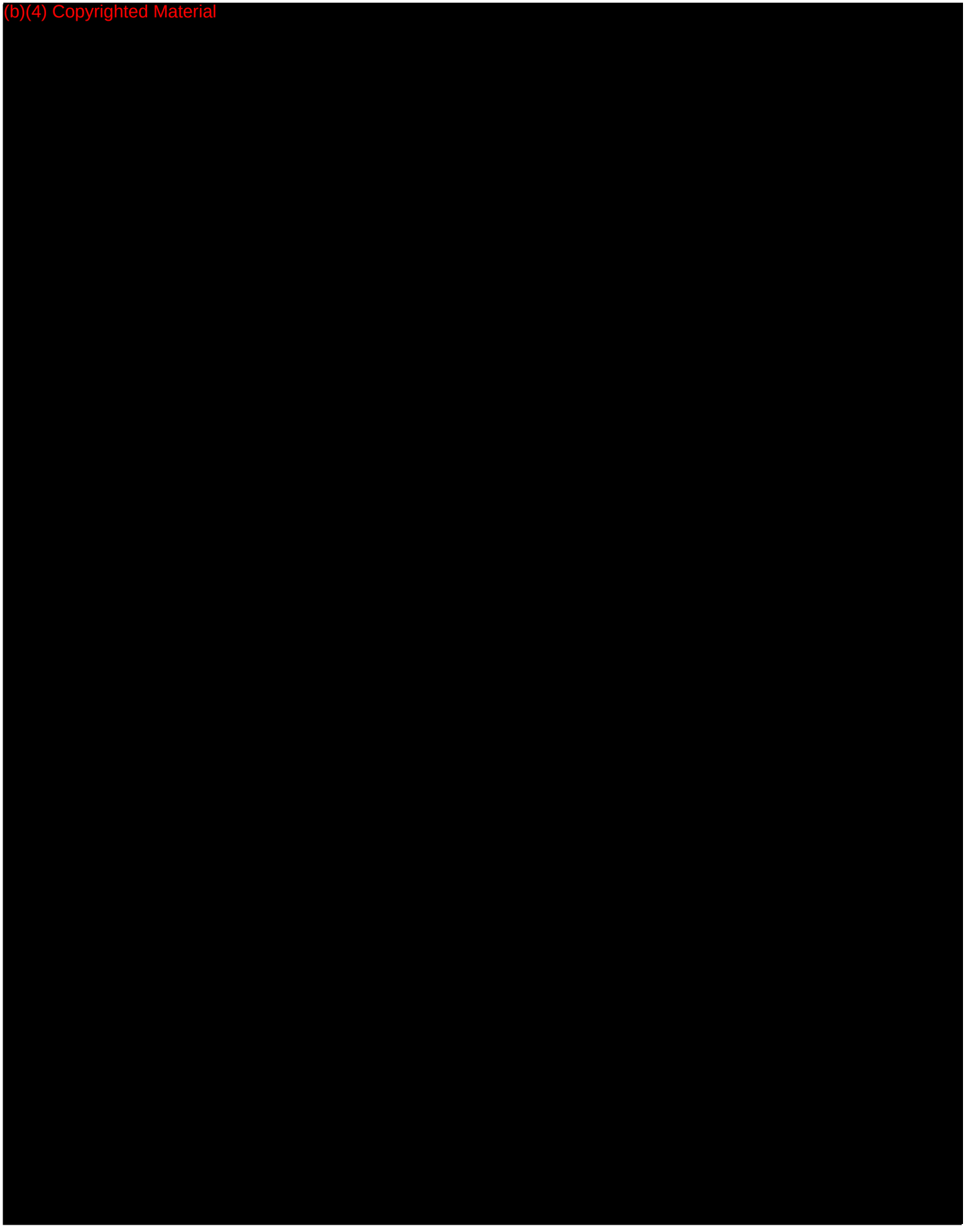
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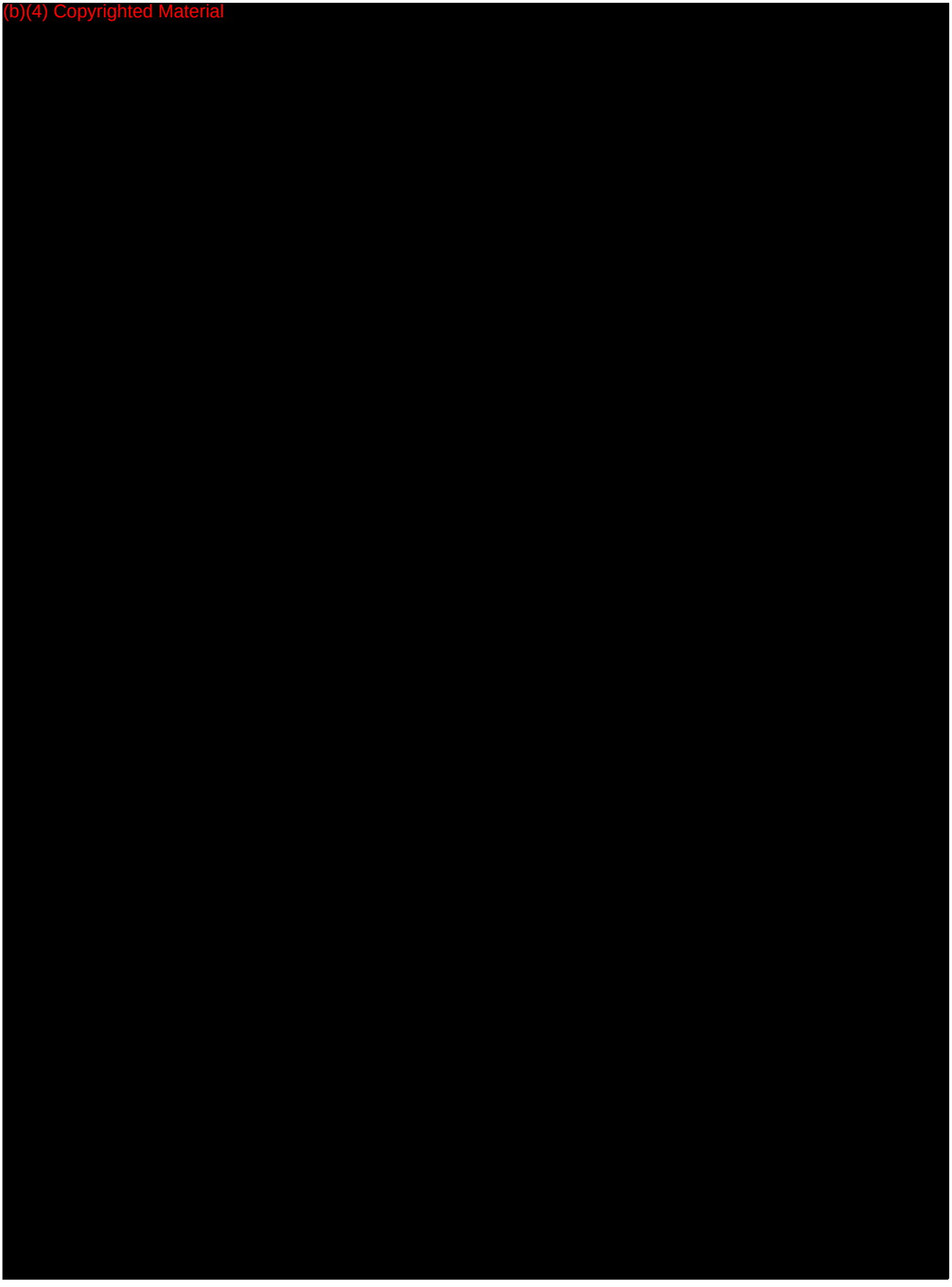
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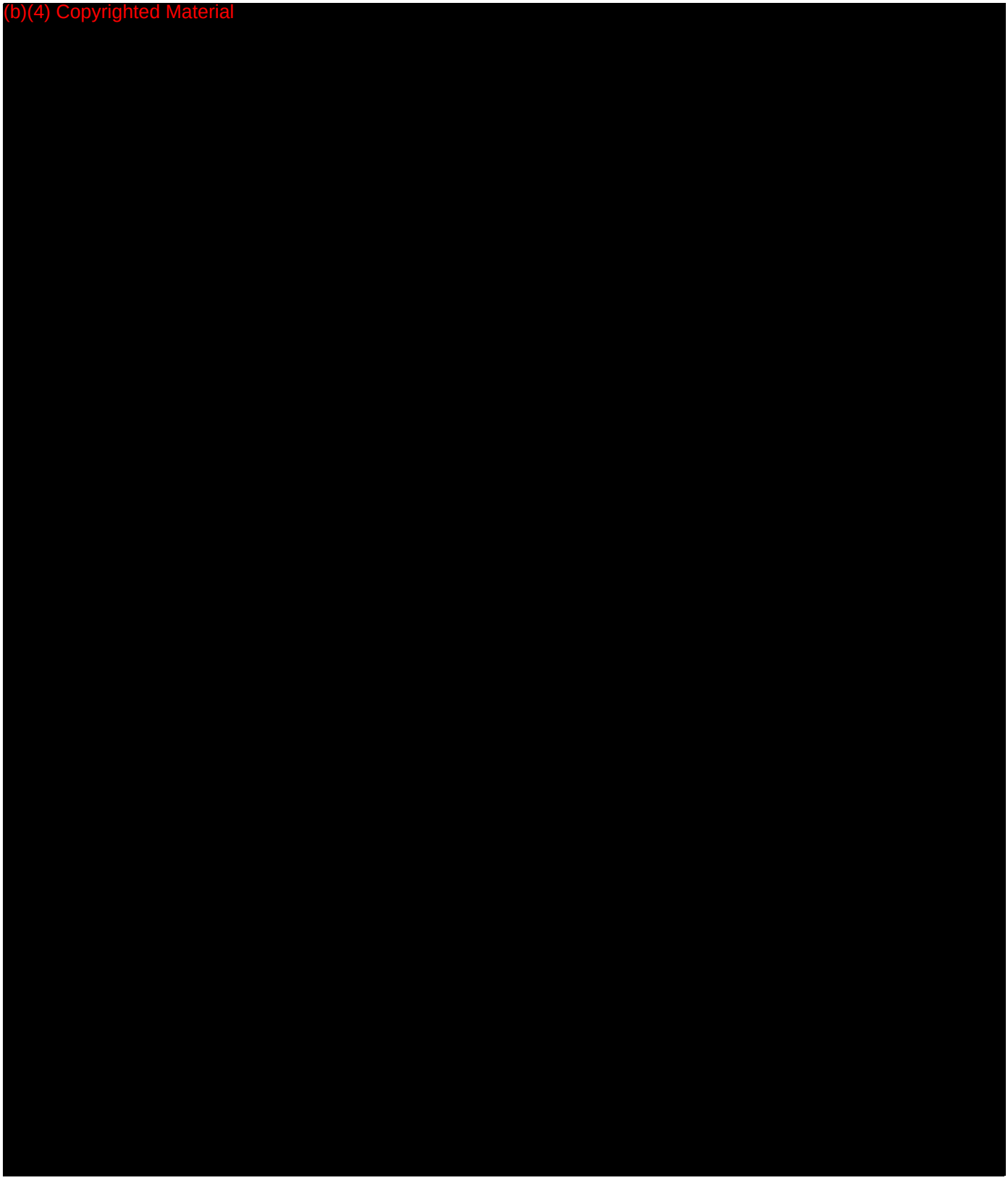
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ORIGINAL ARTICLE

Computer Navigation Did Not Improve Alignment in a Lower-volume Total Knee Practice

W. P. Yau MBBS, FRCSE, FHKCOS,
K. Y. Chiu FHKCOS, J. L. Zuo MD,
W. M. Tang FHKCOS, T. P. Ng FHKCOS

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Abstract Postoperative alignment of the implanted prosthesis in computer-navigated TKA has been reported to be superior to that using the conventional technique. There is an assumption that use of computer navigation techniques can make an inexperienced or occasional TKA surgeon perform more like an expert TKA surgeon. To assess improved accuracy in recreation of mechanical alignment in TKA performed using computer navigation, a retrospective review of the experience of one of the authors (WPY) before and after using computer navigation was performed. We reviewed the radiographic results of 104 TKAs (52 computer navigation, 52 conventional technique) and found the accuracy of postoperative radiographic alignment of the implanted prosthesis was not improved by using computer navigation as judged by (1) overall limb alignment (case: varus 1.3°; control: varus 0.3°); (2) femoral component alignment (case: 90.3°; control: 90.3°); and (3) tibial component alignment (case: 89°; control: 90°). Significant factors that affected postoperative overall mechanical alignment in the current navigation series included severity of the preoperative deformity, amount of error in making bone cuts, and experience of the surgeon in using the computer navigation system.

Level of Evidence: Level III, therapeutic study. See the Guidelines for Authors for a complete description of levels of evidence.

Introduction

Malalignment in TKA can lead to early mechanical failure of the prosthesis [11, 27]. It is recommended that the limb should be aligned so that the two compartments of the TKA are loaded evenly [14, 15]. The postoperative mechanical axis of the lower limb should be a straight line passing through the center of the hip, the center of the knee, and the center of the ankle. However, some authors agree this objective may not be practically obtainable in every TKA [15]. Satisfactory position of a TKA prosthesis is commonly accepted to be an alignment within 3° from this ideal [1, 6, 7, 12, 17, 18, 22, 23, 28, 33]. Aseptic loosening of the prosthesis has been reported to be more common in knees implanted in an alignment greater than 3° varus [26].

Radiographic alignment of the implanted prosthesis in navigated TKA is reported to be superior to that performed by conventional instrumentation [1, 2, 4, 6–8, 12, 13, 17, 20–23, 25, 28, 29, 34]. If an outlier in the lower limb mechanical alignment is defined as greater than 3° from the neutral position, the majority of the TKA series performed using the conventional jig-based technique reported a satisfactory alignment rate of approximately 70% [1–3, 5–10, 12, 13, 16–24, 28, 29, 31–34]. However, the results of most of the computer navigation TKA series were much more favorable, reporting satisfactory alignment of 90% to 100% [1, 17, 22, 23, 28, 29, 34]. Some surgeons have suggested this improved predictability of postoperative radiographic

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Each author certifies that his or her institution has approved the reporting of these cases, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

W. P. Yau (✉), K. Y. Chiu, J. L. Zuo, W. M. Tang, T. P. Ng
Department of Orthopaedic and Traumatology, Queen Mary Hospital, The University of Hong Kong, No 102, Pokfulam Road, Pokfulam, Hong Kong
e-mail: peterwpy@hkucc.hku.hk

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alignment with computer navigation TKA occurs with experienced and inexperienced surgeons [30]. This leads to the assertion that use of the computer navigation technique in TKA can make the inexperienced or occasional TKA surgeon more like the expert TKA surgeon. However, this is not substantiated by the available literature. Because many studies regarding this subject have been performed in high-volume tertiary referral centers, there is concern whether similarly good results can be obtained by the average orthopaedic surgeon [3]. Despite the fact that radiographic alignment of the implanted prosthesis is superior in computer navigation TKA, outliers greater than 3° are still unavoidable in most of the reported series [1, 7, 8, 12, 17, 22, 23]. The potential reasons leading to these outliers are not discussed in adequate detail in the literature.

The aim of this article is to report the radiographic results of a series of computer navigation TKAs done in a hospital with a lower-volume total knee practice. The primary research objective was to examine whether there was improved accuracy in postoperative radiographic alignment of the implanted prosthesis performed using computer navigation TKA versus conventional instrumentation TKA as judged by (1) overall limb alignment relative to the mechanical axis of the lower limb, (2) femoral component alignment relative to the mechanical axis of the femur, and (3) tibial component alignment relative to the mechanical axis of the tibia. The second research objective was to study the factors that affected the accuracy of computer-navigated TKA in regard to (1) overall limb alignment, (2) femoral component alignment, and (3) tibial component alignment. These include patient factors (age, gender, diagnosis, and coronal plane deformity of the knee measured on preoperative standing long films of the whole lower limb) and surgeon factors (experience of the surgeon in performing navigation-based surgery and intraoperative bone cut error).

Materials and Methods

To assess the improved accuracy in recreation of mechanical alignment in the TKA performed using computer navigation, a retrospective review of the experience of one of the authors (WPY) before and after using computer navigation was performed. Patients were recruited into the analysis based on the following inclusion criteria: (1) the operation was primary TKA; (2) the diagnosis was end-stage arthritis of the knee; and (3) the operating surgeon was WPY. Patients were excluded from analysis if malrotation was found in the standing long films of the whole lower limb. The case series was a consecutive series of the author's initial experience using the computer navigation technique from January 2004 to October 2006. The control series was a selected series from matching cases of the author's previous experience using conventional instrumentation (femur intramedullary alignment guide and tibial extramedullary alignment guide) from January 2001 to December 2004. A power analysis was conducted to determine the required sample size. Because the reported percentages of satisfactory lower limb mechanical alignment were 70% to 75% in the majority of conventional technique TKA series [1–3, 5–10, 12, 13, 16–24, 28, 29, 31–34] and 90% to 100% in computer navigation TKA series [1, 17, 22, 23, 28, 29, 34], it was assumed there should be an improvement in satisfactory alignment of at least 15% using the computer navigation technique. The sample size estimation was performed using a power of 80%, a level of significance of 5%, an estimate of a significant reduction of 15% of outliers greater than 3° in mechanical alignment of the lower limb in the computer navigation group when compared with the conventional jig-based group, and an estimate of a standard deviation of 30% in the variation of reported results in the conventional jig-based series. This suggested at least 64 TKAs should be included.

Fifty-four consecutive image-free computer navigation TKAs were performed by the author from January 2004 to October 2006. The author had experience performing 100 conventional technique TKAs (femur intramedullary alignment system and tibia extramedullary alignment system). The average number of TKAs performed each year was approximately 25. The operations were performed using either VectorVision® (BrainLAB AG, Munich, Germany; 15 knees) or Ci™ (BrainLAB; 39 knees) image-free navigation TKA software. Both of these machines were developed by BrainLAB and the software share similar workflow and basic assumptions. The navigation system was used only for navigation of the bone cuts in all cases. Implantation of the prosthesis was not navigated. Standing long radiographs of the whole lower limb were taken 6 weeks after the index operation. The radiographs were repeated if we observed malrotation of the lower limbs on the radiographs. Malrotation was assumed to be present when the femoral condyles were found to be asymmetric or the width of the medial and lateral keels of the tibial tray were not the same. We excluded two knees because of persistent malrotation observed on repeated radiographs of the whole lower limb. One patient had rheumatoid arthritis and one patient had hemophiliac arthropathy. Both had multiple joint involvement stemming from the arthritic situation. Thus, the case series was composed of 52 navigation TKAs. There were eight males and 25 females. Fourteen patients received unilateral TKAs, and 19 patients received one-stage sequential bilateral TKAs. We operated on 49 knees because of

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primary osteoarthritis of the knee and three knees because of rheumatoid arthritis.

We compared this case series with an historical control series of 52 TKAs performed by the author using a conventional instrumentation technique (femur intramedullary alignment guide and tibia extramedullary alignment guide). The historical control series was chosen by the operating surgeon (WPY) on the basis of age, gender, and body height without any information on results of the radiographic measurement (either preoperative or postoperative). No major differences were found between the two series in terms of age, gender, body height, diagnosis leading to the operation, or preoperative lower limb deformity observed on the standing coronal plane radiographs of the whole lower limb (Table 1).

The prosthesis used in the navigation group was a posterior-stabilized design (18 LPS-Flex, Zimmer, Inc, Warsaw, IN; 34 PFC®, DePuy Orthopaedics, Inc, Warsaw, IN). The prosthesis used in the historical control group was an LCS® rotating-platform knee (Depuy).

All radiographic measurements were done using postoperative standing radiographs of the whole lower limb. Mechanical axis of the lower limb, alignment of the femoral prosthesis with respect to the mechanical axis of the femur in the coronal plane, and alignment of the tibial prosthesis with respect to the mechanical axis of the tibia in the coronal plane were determined. Two independent observers (WPY, ZJL) were involved. One of the observers (WPY) was the operating surgeon and the other was an observer (ZJL) who was blinded to the results. Repeated measurements of the radiographs were done with an interval of at least a 1-week between them. Ideal alignment of mechanical axis of the lower limb was defined as a collinear line joining the center of the hip, the center of the prosthetic knee, and the center of the ankle. Ideal alignment of the femoral and tibial prostheses in the coronal plane were defined as an alignment perpendicular to the mechanical axis of the corresponding bone. A surgical outlier was defined as a deviation greater than 3° from the ideal alignment. The results of the two series were compared. The null hypothesis stated there was no difference in postoperative overall limb alignment measured on the standing radiographs of the whole lower limb between computer navigation TKA and conventional technique TKA. This was examined by an independent t test. Statistical significance was assumed if $p < 0.05$.

We studied the potential factors that might affect accuracy of the alignment in the navigation group. These included patient factors (age, gender, diagnosis, and coronal plane deformity of the knee measured on preoperative standing long films of the whole lower limb) and surgeon factors (experience of the surgeon in performing navigation-based surgery and intraoperative bone cut error). We documented intraoperative errors in bone cuts by noting the navigation values recorded at the time of verification of the cut accuracy.

We conducted a literature review of the available reports of image-free navigation TKAs. A Medline search of all available English series of image-free computer navigation TKAs from January 2003 to February 2007 was performed. The series was included in the analysis only if the postoperative radiographic measurement was measured with reference to the mechanical axes of the femur and tibia. Satisfactory alignment of the prosthesis was defined as a deviation of 3° or less from the perpendicular to the corresponding mechanical axis. We identified 13 clinical series for comparison with the current navigation series (Table 2). Seven studies were prospective, randomized studies [1, 7, 23, 25, 28, 29, 34] and six were retrospective case-control series [2, 12, 17, 20–22]. We compared the characteristics of the patients and the radiographic results of the current case series with those in the literature. The average age of the patients in our study was comparable with patient ages in most of the reported series. However, the preoperative coronal plane deformity in our navigation series (varus 3° to varus 38°, average varus 14°) was in general much more severe than reported coronal plane deformities.

Table 1. Demographics of computer navigation TKAs (cases) and conventional jig-based TKAs (controls)

Factor	Computer navigation TKAs (cases)	Conventional jig-based TKAs (controls)	p Value
Age (years)*	69 ± 9.2 (48–89)	66.3 ± 7.6 (49–81)	0.105 (independent t test)
Gender: male/female	8/25	5/28	Chi square 0.99/0.32
Unilateral TKA	14 patients (14 knees)	14 patients (14 knees)	
One-stage sequential bilateral TKAs	19 patients (38 knees)	19 patients (38 knees)	
Diagnosis: osteoarthritis/rheumatoid arthritis	31/2	33/0	Chi square 3.089/0.079
Body height (cm)*	150 ± 8 (124–163)	151 ± 8 (135–172)	0.441 (independent t test)
Preoperative mechanical alignment*	Varus 14° ± 8° (varus 3° to varus 38°)	Varus 13° ± 7° (valgus 1° to varus 34°)	0.85 (independent t test)

* Values are expressed as mean ± standard deviation, with range in parentheses.

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Table 2. Summary of clinical studies of computer navigation TKA

Study	Ethnic origin	Age of patients (years)*	Body height (cm)*	Preoperative deformity*	Postoperative deformity* (satisfactory alignment)	Satisfactory femoral prosthesis alignment	Satisfactory tibial prosthesis alignment
Current study	Asia	69 ± 9.2 (48–89)	150 ± 8 (124–163)	Varus 14° ± 8° (varus 3° to varus 38°)	Varus 1.3° ± 3.3° (71%)	94.3%	86.5%
Sparmann et al. [28]	Germany	67.4			(100%)	100%	82%
Stockl et al. [29]	Austria	68.2		Varus 3°	Varus 0.3° (100%) (± 5°)		
Bathis et al. [1]	Germany	68.7		Varus 8.4°	0° (96%)	92%	98%
Victor and Hoste [34]	Belgium	72	164 (150–176)	Varus 0.4°	0° (100%)		
Matsumoto et al. [22]	Japan				Varus 0.6° (93%)		
Decking et al. [8]	Germany	64.7			Varus 1.5° (52%) (± 2°)		
Kim et al. [17]	United States	68			Varus 0.4° (94%)		
Bolognesi and Hofmann [2]	United States					98%	100%
Haaker et al. [12]	Germany	68	167 (150–188)	Varus 6.3°	Varus 0.77° (79%)		
Chin et al. [7]	Singapore	67.3			Varus 1.58° (80%)	93.3%	93.9%
Martin and Strempel [21]	Austria	70.6		Varus 9°	Varus 2° (81%)	95.2%	95.2%
Matziolis et al. [23]	Germany	71			Varus 1.4° (97%)	100%	100%
Malik et al. [20]	United Kingdom	63.9			Varus 0.68°		

Prosthesis alignment in the coronal plane is considered satisfactory if the absolute error is 3° or less from ideal alignment of the prosthesis in the coronal plane unless specified otherwise: ± 2°, ± 5° = within 2°, 5° from optimal alignment, respectively; *values are expressed as mean ± standard deviation.

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Results

There was no improved accuracy in postoperative radiographic alignment of the implanted prosthesis performed using computer navigation TKA versus conventional instrumentation TKA as judged by the overall alignment relative to the mechanical axis of the lower limb (computer navigation series, varus 1.3° ± 3°; historical control series, varus 0.3° ± 3°; p = 0.1, independent t test; beta error = 0.377) (Table 3). Outliers greater than 3° were observed in 29% of the navigation series and 25% of the conventional jig-based series (p = 0.356, chi square test). Extreme outliers greater than 5° were observed in 10% of the navigation series and 12% of the control series (p = 0.538, chi square test) (Table 4).

There was no statistical difference between the two groups in terms of the error of alignment of the femoral prosthesis in the coronal plane (postoperative distal lateral femoral angle in the navigation series: 90.3° ± 1.9°; control series: 90.3° ± 1.7°; p = 0.999, beta error = 0.05) (Table 3). If a surgical outlier was defined as a deviation greater than 3° from the ideal position, 94.3% of the femoral components in the navigation and conventional technique groups were considered to have satisfactory alignment. One extreme outlier greater than 5° was found in the navigation group but there were none in the control group (Table 4).

The tibial tray was implanted in a slightly more varus alignment in the computer navigation group (postoperative proximal medial tibial angle, 89° ± 2°) than in the conventional technique group (90° ± 2°) (p = 0.01, independent t test) (Table 3). Outliers greater than 3° were found in 13.5% of the tibial components in the navigation group and 9.6% in the control group (p = 0.186, chi square test). No extreme outlier was detected in either group (Table 4).

The significant factors that affected postoperative overall mechanical alignment in the navigation series included severity of the preoperative deformity (p = 0.028, independent t test), amount of error in making bone cuts (p = 0.012, Pearson correlation coefficient = 0.258), and experience of the surgeon (p = 0.023, independent t test) (Table 5). There was a higher error in postoperative mechanical alignment of the whole lower limb if the knee had been more extensively deformed before the operation, if the amount of bone cut errors was greater (Fig. 1), and if it was one of the surgeon's early attempts using computer navigation technology (Fig. 2). Results of the navigation series compared favorably with results of the control series if the surgeon's initial 20 navigation TKAs were removed from the overall case series. The amount of satisfactory lower limb alignment in the last 32 navigation TKAs was 81% (versus control

Table 3. Comparison between alignment of computer navigation TKA and conventional technique TKA

Parameter	Computer navigation TKA*	Conventional technique TKA*	Independent t test
Preoperative mechanical alignment of the lower limb in the coronal plane	Varus 14° ± 8°	Varus 13° ± 8°	p = 0.397 Beta error = 0.134
Postoperative mechanical alignment of the lower limb in the coronal plane	Varus 1.3° ± 3°	Varus 0.3° ± 3°	p = 0.1 Beta error = 0.377
Postoperative distal lateral femoral angle	90.3° ± 1.9°	90.3° ± 1.7°	p = 0.999 Beta error = 0.05
Postoperative proximal medial tibial angle	89° ± 2°	90° ± 2°	p = 0.01 Beta error = 0.743

* Values are expressed as mean ± standard deviation.

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Table 4. Amount of outliers in computer navigation TKAs versus conventional TKAs

Parameter	Computer navigation TKAs (All 52 cases)	Computer navigation TKAs (First 20 cases)	Computer navigation TKAs (subsequent 32 cases)	Conventional TKAs
Postoperative mechanical alignment				
Outlier > 3°	29%	45%	19%	25%
Outlier > 5°	10%	20%	3%	12%
Outlier > 7°	6%	15%	0%	0%
Outlier > 10°	0%	0%	0%	0%
Alignment of femoral components				
Outlier > 3°	5.7%	10%	3%	5.7%
Outlier > 5°	2%	5%	0%	0%
Outlier > 7°	0%	0%	0%	0%
Outlier > 10°	0%	0%	0%	0%
Alignment of tibial components				
Outlier > 3°	13.5%	25%	6%	9.6%
Outlier > 5°	0%	0%	0%	0%
Outlier > 7°	0%	0%	0%	0%
Outlier > 10°	0%	0%	0%	0%

Table 5. Factors affecting results of computer navigated TKA

Factor	Overall limb alignment relative to mechanical axis	Alignment of femoral prosthesis	Alignment of tibial prosthesis
Age	NS (p = 0.743)	NS (p = 0.155)	NS (p = 0.237)
Gender	NS (Type II error = 0.2)	NS (Type II error = 0.081)	p = 0.04
Male	0.3° ± 2.5°	1.3° ± 1°	1.2° ± 1°
Female	1.6° ± 3.5°	1.5° ± 1.2°	2° ± 1.2°
Preoperative alignment	p = 0.028	NS (Type II error = 0.053)	NS (Type II error = 0.342)
Varus > 15°	2.7° ± 3.9°	1.4° ± 1.5°	2.2° ± 0.9°
Varus < 15°	0.6° ± 2.8°	1.5° ± 1°	1.6° ± 1.3°
Diagnosis leading to operation	NS (Type II error = 0.065)	NS (Type II error = 0.087)	NS
Osteoarthritis	1.3° ± 3.4°	1.4° ± 1.2°	1.8° ± 1.1°
Rheumatoid arthritis	0.6° ± 1.4°	1.8° ± 1.4°	1.8° ± 2.4°
Experience of surgeon	p = 0.023	NS (Type II error = 0.065)	p = 0.029
Author first 20 computer navigation TKAs	2.6° ± 3.8°	1.8° ± 1.8°	2.7° ± 1.3°
Author subsequent computer navigation TKAs	0.4° ± 2.7°	1.4° ± 1°	1.6° ± 1.1°
Error in making bone cuts (documented by the navigation machine intraoperatively)	p = 0.012	NS (p = 0.129)	NS (p = 0.308)

Values are expressed as mean ± standard deviation; NS = not significant.

group: 75%; p = 0.166, chi square test). Only 3% of extreme outliers greater than 5° were found (versus 12% in the control group; p = 0.006, chi square test) (Table 4).

Accuracy of the alignment of the implanted femoral prosthesis in the navigation series was not associated with any of the patient or surgeon factors studied (Table 5). However, if the surgeon's early experience using the computer navigation technology was removed from the analysis, 97% of the alignments of the implanted femoral prostheses in the navigation series were satisfactory (control group: 94.3%; p = 0.244, chi square test). No extreme outlier was detected (Table 4).

Accuracy of the alignment of the tibial prosthesis was related to the gender of the patients (p = 0.04, independent t test) and experience of the surgeon (p = 0.029, independent t test) (Table 5). Female gender was associated

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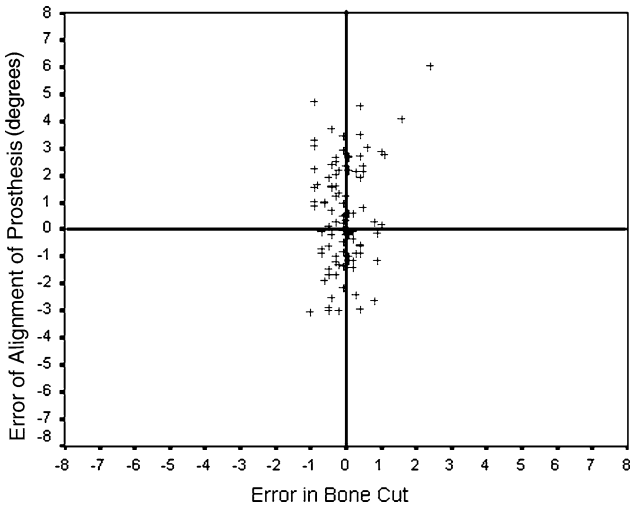


Fig. 1 Error in making bone cuts (with reference to the navigation system) was compared with the error of alignment of the prosthesis on a postoperative radiograph (degrees) (+ = varus error; - = valgus error).

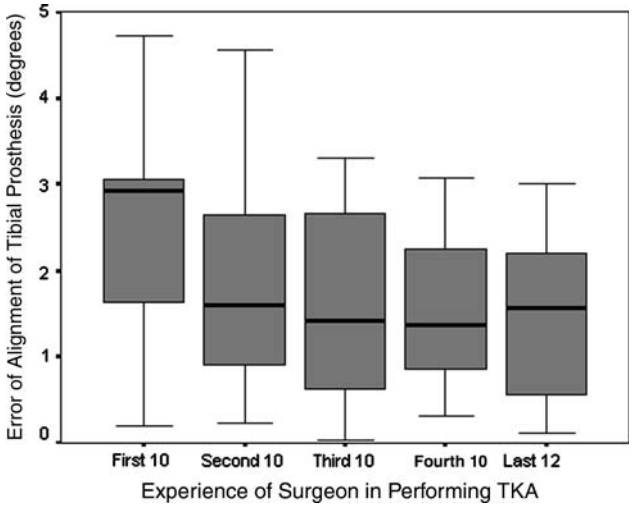


Fig. 2 The experience of the surgeon in performing computer navigation TKA influenced radiographic alignment of the implanted tibial prostheses. The box represents the interquartile range that contains 50% of the value. The whiskers are lines extending from the box to the highest and the lowest values. The horizontal line in the box represents the mean.

with inferior postoperative radiographic alignment of the implanted prosthesis (Table 5). More error was found in the surgeon's first 20 navigation TKAs (Fig. 2). If only the results of the last 32 navigation TKAs were studied, two outliers greater than 3° (6%) were found in the implanted tibial component in the computer navigation series (control group: 9.6%; p = 0.222, chi square test) (Table 4).

There was good intraobserver and interobserver agreement in all of the measurements performed (Table 6).

Table 6. Interobserver and intraobserver error

Parameter	Observer 1		Observer 2		Interobserver error (independent t test)	Intraobserver error (independent t test)
	First measurement*	Second measurement*	First measurement*	Second measurement*		
Postoperative mechanical axis	1.3° ± 3.3°	1.4° ± 3.4°	1.2° ± 3.4°	1.3° ± 3.4°	p = 0.796 Beta error = 0.058	p = 0.944 Beta error = 0.051
Distal lateral femoral angle	90.2° ± 1.9°	90.3° ± 1.9°	90.2° ± 1.9°	90.3° ± 1.9°	p = 0.924 Beta error = 0.051	p = 0.787 Beta error = 0.058
Proximal medial tibial angle	89° ± 1.9°	88.9° ± 1.9°	89.2° ± 1.9°	89.1° ± 1.9°	p = 0.471 Beta error = 0.111	p = 0.674 Beta error = 0.07

* Values are expressed as mean ± standard deviation.

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Discussion

Radiographic alignment of the implanted prosthesis in navigated TKA is reported to be superior to that performed using conventional instrumentation in the majority of published reports [1, 2, 4, 6–8, 12, 13, 17, 20–23, 25, 28, 29, 34]. It is believed the use of computer navigation in TKA can make an inexperienced or occasional TKA surgeon more like an expert TKA surgeon. The objective of our study was to examine whether there was improved accuracy in postoperative radiographic alignment of the implanted prosthesis performed using computer navigation TKA versus conventional instrumentation TKA as judged by (1) overall limb alignment, (2) femoral component alignment, and (3) tibial component alignment. The results of our case-control study did not support the assumption of an automatic advantage. The use of computer navigation technology did not improve the accuracy in recreation of mechanical alignment in TKA when compared with the conventional jig-based technique in a hospital with a lower-volume total knee practice. Alignment of implanted femoral (94.3% satisfactory) and tibial prostheses (86.5% satisfactory) in the current navigation surgery group was good but not superior when compared with that of the historical control group (94.3% and 90.4%, respectively). The volume of the operations performed by the surgeon and the experience in using computer navigation technology might be contributing factors.

The retrospective nature of our case-control series potentially introduced bias during selection of the control group, although the author (WPY) was not aware of the results of radiographic measurement at the time of the selection. The amount of satisfactory overall mechanical alignment (75%) in the control series was comparable with reported amounts [1–3, 5–10, 12, 13, 16–24, 28, 29, 31–34]. (Table 7). However, accuracy of implantation of the femoral and tibial components (94.3% and 90.4% satisfactory, respectively) was better than reported accuracy rates (Table 7). Readers should be aware of the potential bias present in this type of retrospective case-control study. The other two major limitations in the methodology of our study included the use of two navigation systems (despite the fact they were designed by the same company, shared the same operating philosophy, and followed similar workflow) and the difference in the design of the prosthesis used (although the computer navigation technique theoretically should work well regardless of the design of the prosthesis because the focus is on accuracy of the bone cuts, not the specific implant design nor instrumentation used).

Another potential source of error was that the use of the navigation system was limited to the bone cuts and was stopped before final cementing of the implants. Furthermore, we measured postoperative mechanical alignment of the lower limb and positions of the implanted prostheses using standing radiographs of the whole lower limb. There is concern regarding the accuracy of using plain radiographs in this type of assessment, especially if malrotation is present. Despite the attempt to minimize this error by repeating the radiographs if malrotation of the lower limb was observed, readers should be aware of this limitation.

The average postoperative limb alignment relative to the mechanical axis of the lower limb in our navigation series was varus 1.3°. This is comparable with reported alignment (Table 2). If an outlier was defined as greater than 3° from the ideal position, considerably more outliers were found in our navigation series (71% satisfactory alignment) than in the literature (79%-100% satisfactory alignment) (Table 2). The percentage of extreme outliers greater than 5° was as much as 10% (Table 4).

The coronal plane alignment of 94.3% of the femoral prosthesis and 86.5% of the tibial prosthesis in our navigation series were considered satisfactory. The accuracy of the implanted femoral prosthesis with regard to the mechanical axis of the femur was within reported ranges (92%–100% satisfactory) (Table 2). However, the degree of accuracy of the implanted tibial prosthesis achieved in our navigation series generally was less than those in published series (Table 2).

Significant factors that affected postoperative overall mechanical alignment in our navigation series included severity of the preoperative deformity ($p = 0.028$), amount of error in bone cuts ($p = 0.012$), and experience of the surgeon in using the computer navigation system ($p = 0.023$) (Table 5). The preoperative coronal plane deformity in our navigation series (varus 3° to varus 38°; average varus 14°) generally was much more severe than those reported (Table 2). This might partly account for the observed inferior result in our series. The large preoperative deformity might be multiplanar and have resulted in errors in creation of the image-free coordinate system and therefore accounted for some of the imprecision. In addition, accuracy of overall mechanical alignment increased with the experience of the surgeon in using the navigation system (Fig. 2). If the results of the surgeon's first 20 navigation TKAs were removed from the overall analysis, the amount of satisfactory overall mechanical alignment improved from 71% to 81% (Table 4). This still was inferior to those in the majority of reports of computer navigation series (Table 2). Although it was better than that of the historical control series (75% satisfactory), this amount of improvement was not significant ($p = 0.166$, chi square test).

The accuracy of postoperative alignment of the femoral prosthesis in our study was not associated with any

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Table 7. Radiographic alignment of prostheses using conventional jig-based technique*

Study	Overall lower limb alignment	Femoral component	Tibial component
Current study	75%	94.3% (IM)	90.4% (EM)
Sparmann et al. [28]	87%	72%	90%
Bathis et al. [1]	78%	86% (IM)	94% (EM)
Chauhan et al. [6]	71%	91% (IM)	91% (EM)
Bolognesi and Hofmann [2]		90% (IM)	92% (EM)
Chin et al. [7]	63%	65% (IM)	53% (IM)
			84% (EM)
Haaker et al. [12]	72%	88% (IM)	92% (EM)
Kim et al. [17]	73%		
Kim et al. [18]	82%	91% (IM)	93% (EM)
Matziolis et al. [23]	75%	89%	82%
Patil et al. [24]			87% (IM)
Tillett et al. [33]	86%	64% (IM) (±2°)	
		96% (IM) (±4°)	
		68% (EM) (±2°)	
		88% (EM) (±4°)	
Engh and Petersen [10]		88% (IM)	82% (EM) (± 2°)
		69% (EM)	
Matsumoto et al. [22]	67%	70% (± 2°)	77% (± 2°)
Cates et al. [5]	58% (± 2°)	86% (IM)	73% (EM) (± 2°)
		72% (EM)	
Hart et al. [13]	70% (± 2°)		
	93% (± 4°)		
Victor and Hoste [34]	73.5% (± 2°)		
Decking et al. [8]	36% (± 2°)	80% (IM) (± 2°)	80% (EM) (± 2°)
	68% (± 4°)	92% (IM) (± 4°)	96% (EM) (± 4°)
Ishii et al. [16]	96% (± 5°)	90% (IM) (± 4°)	88% (IM) (± 4°)
			88% (EM) (± 4°)
Maestro et al. [19]	89% (± 5°)	96% (IM) (± 4°)	87% (IM) (± 4°)
			84% (EM) (± 4°)
Stockl et al. [29]	94% (± 5°)		
Brys et al. [3]		43% (EM) (± 2°)	94% (IM) (± 2°)
			85% (EM) (± 2°)
Dennis et al. [9]			72% (IM) (± 2°)
			88% (EM) (± 2°)
Teter et al. [31]		91% (IM) (± 4°)	94% (IM) (± 4°)
			92% (EM) (± 4°)

* Satisfactory alignment is defined as within 3° from optimal alignment unless specified otherwise: ± 2°, ± 4°, ± 5° = within 2°, 4°, 5° from optimal alignment, respectively; IM = intramedullary alignment system; EM = extramedullary alignment system.

of the factors investigated (including patient factors and surgeon factors). Removal of the results of the surgeon's first 20 navigation TKAs improved the percentage of satisfactory alignment in the navigation series from 94.3% to 97%. However, this did not result in a significant improvement when compared with the conventional jig-based technique (control group: 94.3%; p = 0.244, chi square test).

More errors were observed in postoperative alignment of the tibial prosthesis in female patients (p = 0.04, independent t test) and the surgeon's first 20 navigated TKAs (p = 0.029, independent t test). The percentage of satisfactory tibial alignment with regard to the mechanical axis of the tibia improved from 86.5% to 94% if the surgeon's early attempts using the navigation system were removed from the analysis. This was comparable to published results

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(Table 2). The difference between accuracy of tibial alignment in the navigation series and the historical control series (90.4%) was not significant ($p = 0.222$, chi square test).

Accuracy in postoperative radiographic alignment of an implanted prosthesis was not improved by using a computer navigation system in a hospital with a lower-volume total knee practice as judged by (1) overall limb alignment relative to mechanical axis of the lower limb (case 71% versus control 75%), (2) femoral component alignment relative to mechanical axis of the femur (case 94.3% versus control 94.3%), and (3) tibial component alignment relative to mechanical axis of the tibia (case 86.5% versus control 90.4%). Significant factors that affected overall postoperative mechanical alignment in the current navigation series included severity of the preoperative deformity ($p = 0.028$), amount of error in making bone cuts ($p = 0.012$), and experience of the surgeon in using the computer navigation system ($p = 0.023$). However, the limitations of our study in terms of its retrospective nature, the use of two navigation systems, the difference in the design of the prostheses used, and the use of plain radiographs for measurement suggest caution in interpreting these results.

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INTERPRETATION OF SYMBOLS

SIGNIFICATION DES SYMBOLES

BEDEUTUNG DER SYMBOLE

INTERPRETACIÓN DE SÍMBOLOS

INTERPRETAZIONE DEI SIMBOLI

INTERPRETAÇÃO DE SÍMBOLOS

BETEKENIS VAN DE SYMBOLEN

BETYDNING AF SYMBOLER

FÖRKLARNING AV OLIKA SYMBOLERS BETYDELSE

SYMBOLIEN SELITYKSET

EPMHNEIA ΣΥΜΒΟΛΩΝ

VYSVĚTLIVKY VÝRAZŮ A SYMBOLŮ

MAGYARÁZAT A HASZNÁLT JELEKHEZ ÉS KIFEJÉZÉSEKHEZ

ZNACZENIE SYMBOLI I TERMINÓW

VYSVETLENIE TERMÍNOV A SYMBOLOV

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Symbol to be Included in IFU	Interpretation	Symbol(s)
✓	DEPUY, INC.	D/DP
✓	QUANTITY	QTY
✓	MATERIAL	MATL
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✓	SIZE	SIZE and SZ
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* **DePuy (Ireland)**
Loughbeg, Ringaskiddy
Co. Cork
Ireland
Tel: +353 214914278
Fax: +353 214914199

* **DePuy Orthopaedics, Inc**
700 Orthopaedic Drive
Warsaw, IN 46582
USA
Tel: 1 +(800) 366 8143

* **DePuy International Ltd.**
St. Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 270 0461
Fax: +44 (113) 272 4101

*** For recognized manufacturer, refer to product label.**

US REP **DePuy Orthopaedics, Inc.**
700 Orthopaedic Drive
Warsaw, IN 46582
USA
Tel: 1 +(800) 366 8143

EC REP **DePuy International Ltd.**
St. Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (113) 270 0461
Fax: +44 (113) 272 4101

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Rev. ~~C~~D

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K110397/52
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FDA CDRH DMC
JUN 06 2011
Received

June 3, 2011

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

Re: K110397, TruMatch™ Patient Specific Instruments-Responses to (b)(4) related questions dated April 27, 2011

Dear Dr. Beardsley:

DePuy Orthopaedics, Inc. is submitting responses to the request for additional information (dated April 27, 2011) regarding (b)(4) relating to the TruMatch Patient Specific Instruments (K110397). These responses are submitted in duplicate (one paper and one CD). DePuy certifies that the .pdf file provided on the CD is an exact duplicate of the paper copy of these responses.

To facilitate review, a table of contents with page numbers and tabbed sections has been provided. Each section repeats the question which is being addressed and clearly provides the response to the additional information questions.

Pursuant to 21 CFR 807.9 (c)(3), DePuy considers this 510(k) response to be confidential commercial information and requests that FDA treats it as such. DePuy has taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Please note that additional non-software questions for K110397 were received via email dated June 1, 2011. These questions will be responded to under a separate document as promptly as feasible.

Thank you in advance for your prompt review of these responses. Please contact me by phone at (574) 371-4923, by email at nfriddle@its.jnj.com, of by FAX at (574) 371-4987 if you have further questions or need clarification on anything contained in these responses. Alternatively, you may contact Janet Johnson at (574) 372-7469 or by email at Jjohns70@its.jnj.com

Sincerely,

Nancy Friddle

Nancy Friddle
Project Manager, Regulatory Affairs

PO Box 988, 700 Orthopaedic Drive, Warsaw, IN 46581-0988
Phone 574-267-8143 Fax 574-371-4865

0001

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

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June 3, 2011

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Sincerely,

Nancy Friddle

Nancy Friddle
Project Manager, Regulatory Affairs

PO Box 988, 700 Orthopaedic Drive, Warsaw, IN 46581-0988
Phone 574-267-8143 Fax 574-371-4865

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SECTION 1

Question #1:

(b)(4) Deficiencies

[redacted]

Answer #1:

(b)(4) Deficiencies

[redacted]

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Exhibit A1

Software Hazard Analysis Document ([redacted])

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Software Hazard Analysis
DePuy Orthopaedics Inc.
TruMatch™

	NAME	DATE
PREPARED BY:	(b)(6)	5/24/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/25/2011
APPROVED BY:		5/25/2011
APPROVED BY:		5/25/2011
APPROVED BY:		5/25/2011
APPROVED BY:		5/25/2011
APPROVED BY:		5/25/2011

Prepared by:
(b)(4)

Prepared for:
DePuy Orthopaedics Inc.

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(b)(4) Software Hazard Analysis

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SECTION 2

(b)(4) Deficiencies

[redacted]

Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Exhibit B

Software Design Document (b)(4)

Redacted under FOIA request #2016-826, Released by CDRH on 11-01-2016

Software Design Document
DePuy Orthopaedics Inc.
TruMatch™ TeamCenter Surgeon Interface

	NAME	DATE
PREPARED BY:	(b)(6)	05/17/2011
APPROVED BY:		05/24/2011
APPROVED BY:		05/24/2011
APPROVED BY:		05/24/2011
APPROVED BY:		05/25/2011
APPROVED BY:		05/24/2011

Prepared by:
(b)(4)

Prepared for:
DePuy Orthopaedics Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Received under FOIA Request #2013-826, Released by CDRH on 11-01-2013

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(b)(4) Deficiencies



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Exhibit C

Software Traceability Analysis ([redacted])

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

Test Traceability Analysis
DePuy Orthopaedics Inc.
TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6)	05/25/2011
APPROVED BY:		05/25/2011
APPROVED BY:		05/25/2011
APPROVED BY:		05/25/2011
APPROVED BY:		05/25/2011
APPROVED BY:		05/25/2011

Prepared by:
(b)(4)

Prepared for
DePuy Orthopaedics

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SECTION 4

(b)(4) Deficiencies

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Exhibit D

Software Development Plan ([redacted])

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Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Software Design and Development Plan DePuy Orthopaedics Inc. TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6)	4/29/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/25/2011
APPROVED BY:		5/25/2011
APPROVED BY:		5/24/2011

Prepared by:
(b)(4)

Prepared for:
DePuy Orthopaedics Inc.

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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

(b)(4) Software Development Plan

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SECTION 5

(b)(4) Deficiencies

[redacted]

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Exhibit E

Software Verification Plan (b)(4) (b

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

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Verification Plan
DePuy Orthopaedics Inc.
TruMatch™ Software

PREPARED BY:	(b)(6) [redacted]	03/07/2011
REVIEWED BY:		03/14/2011
REVIEWED BY:		03/14/2011
APPROVED BY:		03/14/2011
APPROVED BY:		03/14/2011
APPROVED BY:		03/14/2011
APPROVED BY:		03/14/2011
APPROVED BY:		03/14/2011
APPROVED BY:		03/14/2011
APPROVED BY:		03/14/2011

Prepared by:
(b)(4) [redacted]

Prepared for
DePuy Orthopaedics Inc.

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(b)(4) Verification Plan

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Exhibit F

Software Verification Protocol ([redacted])

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Software Verification Protocol
DePuy Orthopaedics Inc.
TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6)	05/26/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011

Prepared by:
(b)(4)

Prepared for
DePuy Orthopaedics Inc.

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(b)(4) Software Verification Protocol

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Exhibit G

Code Review Report (b)(4)

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

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Code Review Report
DePuy Orthopaedics, Inc.
TruMatch™ TeamCenter Surgeon Interface

	NAME	DATE
PREPARED BY:	(b)(6)	03/09/2011
REVIEWED BY:		03/20/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011
APPROVED BY:		03/21/2011

Prepared by:
(b)(4)

Prepared for
DePuy Orthopaedics, Inc.

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Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Exhibit H

Software Verification Report (b)(4)

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Records processed under FOIA Request # 2016-626; Released by CDRH on 11-01-2016

Software Verification Report
DePuy Orthopaedics Inc.
TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6) [redacted]	05/25/2011
APPROVED BY:		05/25/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011

Prepared by:
(b)(4) [redacted]

Prepared for
DePuy Orthopaedics Inc.

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Software Verification Protocol
DePuy Orthopaedics Inc.
TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6) [redacted]	05/19/2011
APPROVED BY:		5/23/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/25/2011

Prepared by:
(b)(4) [redacted]

Prepared for
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Exhibit I

Verification Summary Report (b)(4)

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Verification Summary Report
DePuy Orthopaedics, Inc.
TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6)	05/25/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011
APPROVED BY:		05/26/2011

Prepared by:
(b)(4)

Prepared for
DePuy Orthopaedics, Inc.

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SECTION 6

(b)(4) Deficiencies

[redacted]

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(b)(4) Deficiencies



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Exhibit J

Software Requirements Specification (b)(4) [redacted]

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

Released by CDRH on 11-01-2016

Software Requirement Specification
DePuy Orthopaedics
TruMatch™ Software

	NAME	DATE
PREPARED BY:	(b)(6)	5/06/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/24/2011
APPROVED BY:		5/25/2011
APPROVED BY:		5/24/2011

Prepared by:
(b)(4)

Prepared for
DePuy Orthopaedics

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