K030354

MAY 2 0 2003

510(k) Summary

Sponsor:	Skeletal Kinetics, LLC 10201 Bubb Road, Cupertino, CA 95014
Contact Person:	Duran Yetkinler, M.D., Ph.D.
Phone Number:	408 366 5002
Fax Number:	408 366 1077
Prepared:	February 18, 2003

Trade Name:	Callos™
Common Name:	Bone Graft Substitute
Classification:	Unclassified
Product Code:	87 MVQ

Predicate Device: Callos Bone Void Filler is substantially equivalent to Norian SRS Bone Void Filler (K011897).

Device Description: Callos Bone Void Filler is an injectable, moldable and biocompatible bone void filler. Callos Bone Void Filler resorbs and is replaced with bone during the healing process. The 3 cc, 5 cc, and 10 cc Callos Bone Void Filler kits are provided sterile and are for single use only.

Intended Use/Indications for Use: Callos Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Technological Characteristics: Similar to the predicate device, Callos Bone Void Filler is an injectable, moldable, biocompatible, resorbable calcium phosphate based material intended for identical indications.

Performance Data: Non-clinical testing included material properties such as density, porosity, dimensional stability, injectability, setting time, working time, pH, and setting temperature. Biocompatibility testing demonstrated that the material is non-cytotoxic, non-systemic toxic, non-mutagenic, non-irritative, non-pyrogenic, and non-sensitizing. Comparative testing with the predicate device showed equivalence in terms of solubility and dissolution rate, X-Ray Diffraction (XRD), Fourier Transform Infrared (FTIR) spectroscopy and elemental analysis. Animal testing demonstrated substantial equivalence to the predicate device following *in vivo* implantation. Histological, chemical, crystallographical, and mechanical analyses showed substantial equivalence.

Basis for Substantial Equivalence: The Callos Bone Void Filler has the same intended use, identical indications, and very similar technological characteristics as the predicate device. Any minor technological differences between Callos Bone Void Filler and its predicate device do not raise any new issues of safety or effectiveness.

Functional, biocompatibility, and animal testing results show that the Callos Bone Void Filler is as safe and effective as the predicate device. Thus, the Callos Bone Void Filler is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2003

Skeletal Kinetics, LLC
c/o Mr. Howard Holstein
Regulatory Counsel
Hogan & Hartson, LLC
555 13th Street, N.W.
Washington, DC 20004

Re: K030554
Trade/Device Name: Callos™ Bone Void Filler
Regulatory Class: Unclassified
Product Code: MQV
Dated: February 20, 2003
Received: February 21, 2003

Dear Mr. Holstein:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Indications for Use

510(k) Number (if known): K030554

Device Name: Callos Bone Void Filler

Indications for use:

Callos Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

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

510(k) Number K030554

Add to file

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2003

Duran N. Yetkinler, M.D., Ph.D.
VP of Regulatory and Product Development
Skeletal Kinetics, LLC
10201 Bubb Road
Cupertino, CA 95014

Re: K030554
Trade/Device Name: Callos™ Bone Void Filler
Regulatory Class: Unclassified
Product Code: MQV
Dated: February 20, 2003
Received: February 21, 2003

Dear Dr. Yetkinler:

This letter corrects our substantially equivalent letter of May 20, 2003, regarding the contact and address.

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 (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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Sloan, Nadine Y.

From: duran yetkinler [duran@skeletalkinetics.com]
Sent: Monday, June 09, 2003 4:31 PM
To: 'Sloan, Nadine Y.'
Subject: RE: Primary contact person and address change request

Nadine,

Hope all is well. I was following up on the request that I made regarding changing the name and address of the contact person. Any improvements? It turns out that we really want to make this change, so please advise me If I need to write any official letter. Thank you.

Best Regards,

Duran

Duran N Yetkinler MD PhD
VP of Regulatory and Product Development
Skeletal Kinetics, LLC
10201 Bubb Road
Cupertino, CA 95014
Phone 408 366 5002
Fax 408 366 1077
Cell 408 757 6603

-----Original Message-----
From: Sloan, Nadine Y. [mailto:NYR@CDRH.FDA.GOV]
Sent: Friday, May 23, 2003 10:50 AM
To: 'duran yetkinler'
Subject: RE: Primary contact person and address change request

Duran,

Thank you for the information. I will look into this further and see about issuing a correction letter. I will get back to you sometime next week.

Sincerely,

Nadine

-----Original Message-----
From: duran yetkinler [mailto:duran@skeletalkinetics.com]
Sent: Friday, May 23, 2003 1:59 PM
To: NYR@CDRH.FDA.GOV
Subject: Primary contact person and address change request

Nadine,

I have received the substantial equivalence letter, K030554 dated May 20, 2003, for our product Callos. I noticed on the letter that the letter was addressed to Howard Holstein and his address. Howard Holstein and his group act as our regulatory consultant to us, but we would like to keep the primary contact person and address for Skeletal Kinetics as myself and Skeletal Kinetics address. The full name and address for Skeletal Kinetics are given below. I am requesting to make these changes on our files, so that any future and present confusions will be avoided. Thank you for your

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cooperation.

Sincerely,

Duran

Duran N Yetkinler MD PhD
VP of Regulatory and Product Development
Skeletal Kinetics, LLC
10201 Bubb Road
Cupertino, CA 95014
Phone 408 366 5002
Fax 408 366 1077
Cell 408 757 6603

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2003

Skeletal Kinetics, LLC
c/o Mr. Howard Holstein
Regulatory Counsel
Hogan & Hartson, LLC
555 13th Street, N.W.
Washington, DC 20004

Re: K030554
Trade/Device Name: Callos™ Bone Void Filler
Regulatory Class: Unclassified
Product Code: MQV
Dated: February 20, 2003
Received: February 21, 2003

Dear Mr. Holstein:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Indications for Use

510(k) Number (if known): K030554

Device Name: Callos Bone Void Filler

Indications for use:

Callos Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

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

510(k) Number K030554

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 21, 2003

SKELETAL KINETICS, LLC
C/O HOGAN & HARTSON, LLC
555 13TH STREET N.W.
WASHINGTON, DC 20004
ATTN: HOWARD HOLSTEIN

510(k) Number: K030554
Received: 21-FEB-2003
Product: CALLOS

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC 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 www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

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

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K030554

February 20, 2003

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center, HFZ-401
9200 Corporate Drive
Rockville, MD 20850

Re: 510(k) Notification—Bone Void Filler

Dear Madam/Sir:

Enclosed is a submission pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act and the regulations contained in 21 CFR 807.

The purpose of this submission is to notify the FDA of our intent to market a bone void filler. Skeletal Kinetics' bone void filler, Callos™, is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process. Callos will be marketed as a kit comprised of a powder (calcium phosphate source), liquid (dilute sodium silicate), mixing bowl, pestle and spatula. The user empties the contents of both vials into the mixing bowl, and mixes them using the pestle. The spatula is used to transfer the material into a commercially available syringe, which is used to inject the material into the bony void. This kit will be provided as a single use, sterile product packaged in a double sterile barrier using industry standard peel pouches.

Skeletal Kinetics' bone void filler is substantially equivalent to other bone void fillers that are commercially available. The following documents were used in making this determination:

> Orthopedic Devices Branch ODE. Draft guidance document for the preparation of pre-market notification applications for orthopedic devices—the basic elements. FDA: July 16, 1997.
>
> Restorative Devices Branch ODE. Class II special controls guidance document: resorbable calcium salt bone void filler device: draft guidance for industry and FDA. FDA: February 7, 2002.

OK
Unclassified

SK5

Please direct any questions concerning this submission to me at 408.366.5002, or Howard Holstein at 202.637.5813. I also request that FDA notify Skeletal Kinetics, LLC of substantial equivalence by sending a facsimile to me at 408.366.1077.

The Company is aware of its obligations to pay user fee upon invoice.

Thank you in advance for your prompt attention to this submission.

Sincerely,

Duran N. Yetkinler

Duran Yetkinler, M.D., Ph.D.
Director of Clinical and Regulatory Affairs

Enclosure

CDRH SUBMISSION COVER SHEET

Date of Submission: **FDA Document Number:**

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular	☐ Presubmission Summary	Original Submission	☐ Pre-IDE
☐ Modular Submission	☐ Special	☐ Original PDP	X Traditional	☐ Pre-PMA
☐ Amendment	☐ Panel Track	☐ Notice of intent to start clinical trials	☐ Special	☐ Pre-PDP
☐ Report	☐ 30-day Supplement	☐ Intention to submit Notice of Completion	☐ Abbreviated	☐ 180 -day
☐ Report Amendment	☐ 30-day Notice	☐ Notice of Completion	Additional Information	☐ Other (specify):
	☐ 135-day Supplement	☐ Amendment to PDP	☐ Traditional	
	☐ Real-time Review	☐ Report	☐ Special	
	☐ Amendment to PMA Supplement		☐ Abbreviated	
			☐ Report Amendment	

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Class III Designation	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	Describe Submission:
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Amendment	
☐ *Supplement*	☐ *Supplement*		☐ *Supplement*	
	☐ Report			

Section B Applicant or Sponsor

Company/Institution Name **Skeletal Kinetics, LLC**		Establishment registration number **Skeletal Kinetics has filed an initial device establishment registration form, but FDA has not yet assigned an establishment registration number.** **Owner/Operator number: 9054231**	
Division Name (if applicable):		Phone number (include area code) **408-366-5002**	
Street Address **10201 Bubb Road**		Fax number (include area code) **408-366-1077**	
City **Cupertino**	State/Province **CA**	Zip code **95014-4167**	Country **USA**
Contact Name **Duran N. Yetkinler MD, PhD**			
Contact Title **Director of Clinical and Regulatory Affairs**		Contact e-mail address **duran@skeletalkinetics.com**	

Section C Submission Correspondent (if different from above)

Company/Institution Name **Hogan & Hartson, LLC**		Establishment registration number **n/a**	
Division Name (if applicable):		Phone number (include area code) **202-637-5813**	
Street Address **555 13th Street N.W.**		Fax number (include area code) **202-637-5910**	
City **Washington**	State/Province **DC**	Zip code **20004**	Country **USA**
Contact Name **Howard Holstein, Esq.**			
Contact Title **Regulatory Counsel**		Contact e-mail address **HMHolstein@hhlaw.com**	

Section D1 Reason for Submission --- PMA, PDP or HDE		
☐ New Device	☐ Change in design, component or specification	☐ Location Change
☐ Withdrawal	☐ Software	☐ Manufacturer
☐ Additional or expanded indications	☐ Color Additive	☐ Sterilizer
☐ Licensing agreement	☐ Material	☐ Packager
☐ Processing change	☐ Specifications	☐ Distributor
☐ Manufacturing	☐ Other (specify below)	☐ Report Submission
		☐ Annual or Periodic
☐ Sterilization	☐ Labeling changes	☐ Post Approval Study
☐ Packaging	☐ Indications	☐ Adverse Reaction
☐ Other (specify below)	☐ Instructions	☐ Device Defect
☐ Response to FDA correspondence	☐ Performance Characteristics	☐ Amendment
☐ Request for applicant hold	☐ Shelf Life	☐ Change in ownership
☐ Request for removal of applicant hold	☐ Trade Name	☐ Change in Correspondent
☐ Request for extension	☐ Other (specify below)	
☐ Request to remove or add manufacturing site		
☐ Other reason (specify)		

Section D2 Reason for Submission --- IDE		
☐ New Device	Change in	☐ Response to FDA letter concerning
☐ Addition of institution	☐ Correspondent	☐ Conditional approval
☐ Expansion/extension of study	☐ Design	☐ Deemed approval
☐ IRB certification	☐ Informed consent	☐ Deficient final report
☐ Request hearing	☐ Manufacturer	☐ Deficient progress report
☐ Request waiver	☐ Manufacturing process	☐ Deficient investigator report
☐ Termination of study	☐ Protocol -- feasibility	☐ Disapproval
☐ Withdrawal of application	☐ Protocol -- other	☐ Request extension for time to respond to FDA
☐ Unanticipated adverse effect	☐ Sponsor	☐ Request meeting
☐ Notification of emergency use	☐ Report Submission	
☐ Compassionate use request	☐ Current investigator	
☐ Treatment IDE	☐ Annual progress	
☐ Continuing availability request	☐ Site waiver limit reached	
☐ Other reason (specify)	☐ Final	

Section D3 Reason for Submission --- 510(k)		
X New Device		
☐ Additional or expanded indications	☐ Change in Technology	☐ Change in materials
☐ Other reason (specify)	☐ Change in Design	☐ Change in manufacturing process

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Section E Additional Information on 510(k) Submissions				
Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning safety and effectiveness data
1 **MQV**	2	3	4	X 510(k) summary attached
5	6	7	8	☐ 510(k) statement

510(k) Number	Trade of Proprietary or Model Name	Manufacturer
1 **K011897**	1 **Norian SRS Bone Void Filler**	1 **Synthes USA**
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F Product Information – Applicable to All Applications					
Common or usual name or classification name **Bone Void Filler**					
Trade or proprietary or model name			Model Number		
1 **Callos™**			1 **n/a**		
2			2		
3			3		
4			4		
5			5		
FDA document numbers of all prior related submissions (regardless of outcome)					
1	2	3	4	5	6
7	8	9	10	11	12
Data included in submission	X Laboratory testing		X Animal trials	☐ Human trials	

Section G Product Classification – Applicable to All Applicants		
Product code: **MQV**	C.F.R. Section **21 CFR§..... (unclassified)**	Device Class
Classification Panel **Orthopedic devices branch 87**		☐ Class I ☐ Class II ☐ Class III X Unclassified
Indications (from labeling) **Callos Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.**		

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Note: submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.			FDA Document Number
Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission			
X Original ☐ Add ☐ Delete	FDA Establishment Number	X Manufacturer ☐ Contract manufacturer	☐ Contract Sterilizer ☐ Repackager/relabeler
Company/Institution name **Skeletal Kinetics, LLC**		Establishment registration number **Skeletal Kinetics has filed an initial device establishment registration form, but FDA has not yet assigned an establishment registration number** **Owner/Operator number: 9054231**	
Division name (if applicable)		Phone number (include area code) **408-366-5002**	
Street address **10201 Bubb Road**		FAX number (include area code) **408-366-1077**	
City **Cupertino**	State/Province **CA**	Zip code **95014-4167**	Country **USA**
Contact name **Duran N. Yetkinler MD, PhD**			
Contact title **Director of Clinical and Regulatory Affairs**		Contact e-mail address **duran@skeletalkinetics.com**	
X Original ☐ Add ☐ Delete	FDA Establishment Number (b)	☐ Manufacturer ☐ Contract manufacturer	X Contract Sterilizer ☐ Repackager/relabeler

(b) (4)

X Original ☐ Add ☐ Delete	FDA Establishment Number (b)(4)	☐ Manufacturer ☐ Contract manufacturer	X Contract Sterilizer ☐ Repackager/relabeler

(b) (4)

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Table of Contents

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I. Administrative Documents

1. 510(k) Elements Checklist

Page 1 of 3

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

X Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	**Inadequate or Missing**
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	p.1	
Table of Contents.	p.7	
Truthful and Accurate Statement.	p.11, (App A)	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	p.12	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	p.12	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	p.41 (App H & I)	
Statement of Indications for Use that is on a separate page in the premarket submission.	p.11 (App. B)	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	p.42	
510(k) Summary or 510(k) Statement.	p.11	

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	(App. C)	
510(k) Elements Checklist Page 2 of 3		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	p.12	
Identification of legally marketed predicate device. *	p.42	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	p.12, p.21	
Class III Certification and Summary. **	n/a	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	n/a	
510(k) Kit Certification ***	n/a	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission: Not Applicable

Section 3: Required Elements for an ABBREVIATED 510(k)* submission: Not Applicable

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	**Inadequate or Missing**
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	p.13	
b) Sterilization and expiration dating information:	p.41	
i) sterilization process	p.41	

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510(k) Elements Checklist Page 3 of 3		
ii) validation method of sterilization process	p.41	
iii) SAL	p.41	
iv) packaging	p.41	
v) specify pyrogen free	p.41	
vi) ETO residues	n/a	
vii) radiation dose	p.41	
c) Software Documentation:	n/a	

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the " Missing" column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No

Reviewer:_____

Concurrence by Review Branch:_____

Date:_____

The deficiencies identified above 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/cdrh/modact/leastburdensome.html

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2. 510(k) Truthful and Accurate Statement

Please see Appendix A for the 510(k) Truthful and Accurate Statement.

3. 510(k) Indications for Use

Please see Appendix B for the 510(k) Indications for Use.

4. 510(k) Summary

Please see Appendix C for the 510(k) Summary

II. Subject Device

1. Device Description

a. Device Name
Callos Bone Void Filler

b. Sponsor Registration Number
Skeletal Kinetics, LLC has applied for an establishment registration number, but FDA has not yet assigned an establishment registration number. However, FDA has informed Skeletal Kinetics, LLC that the Company is considered to be registered. Skeletal Kinetics' Owner/Operator No is 9054231.

c. Classification
FDA has proposed to classify resorbable calcium salt bone void fillers as Class II devices, but the Agency has not finalized that proposed rule. Currently Callos is an unclassified Bone Graft Substitute.

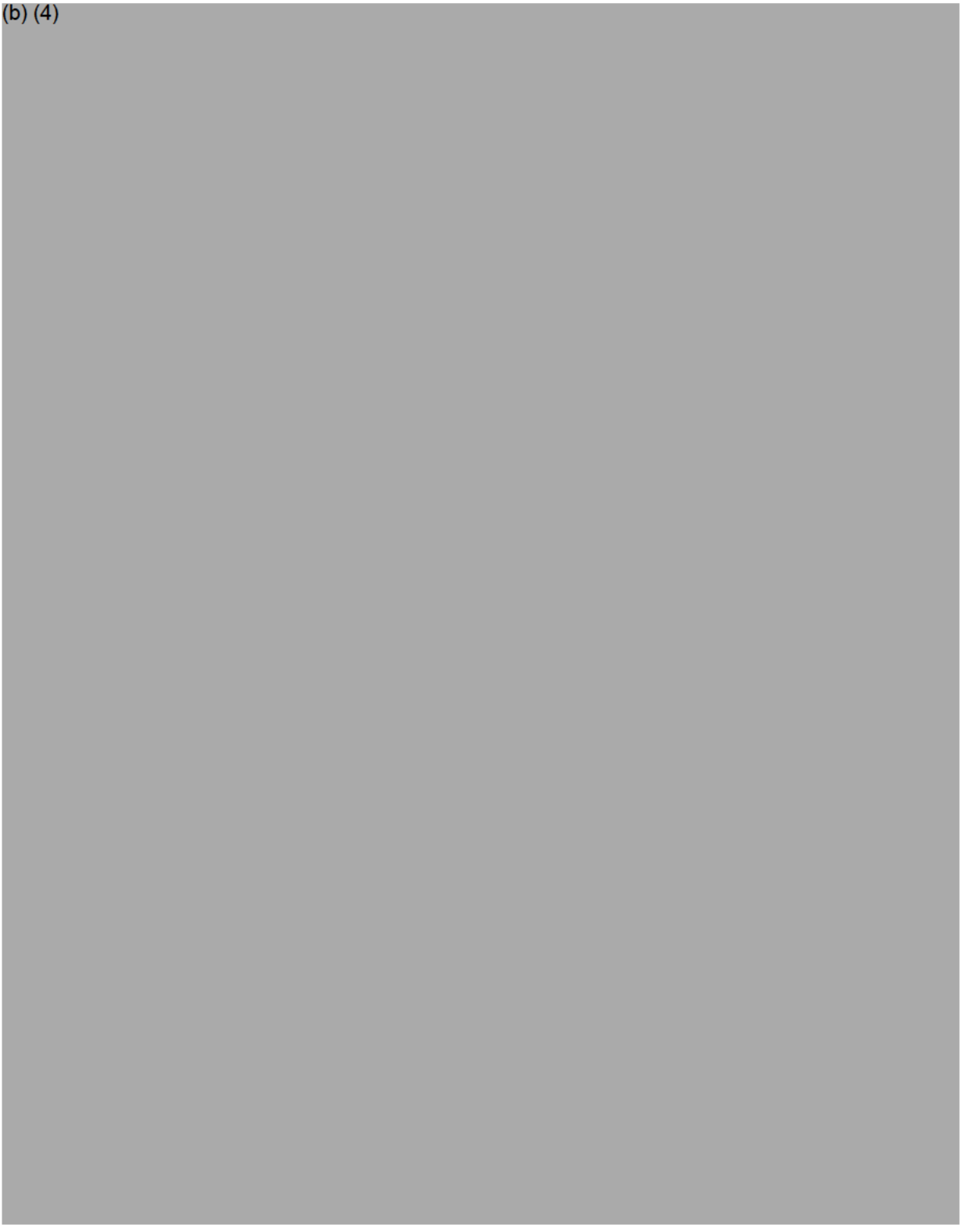
d. Indications for Use
Callos Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

e. Consensus Standards
Elemental analysis of Callos Bone Void Filler shows that the device conforms to USP National Formulary (NF) of "Official Monograph of Calcium Sulfate" for applicable items including Iron and Heavy Metal limits, and to USP National Formulary (NF) of "Official Monograph for Tribasic Calcium Phosphate" for applicable items including Arsenic and Heavy Metal limits.

ASTM F1185-88 "Standard Specification for Composition of Ceramic Hydroxyapatite for Surgical Implants" was withdrawn prior to preparation of this 510(k); therefore no comparison was made to this standard.

2. Testing

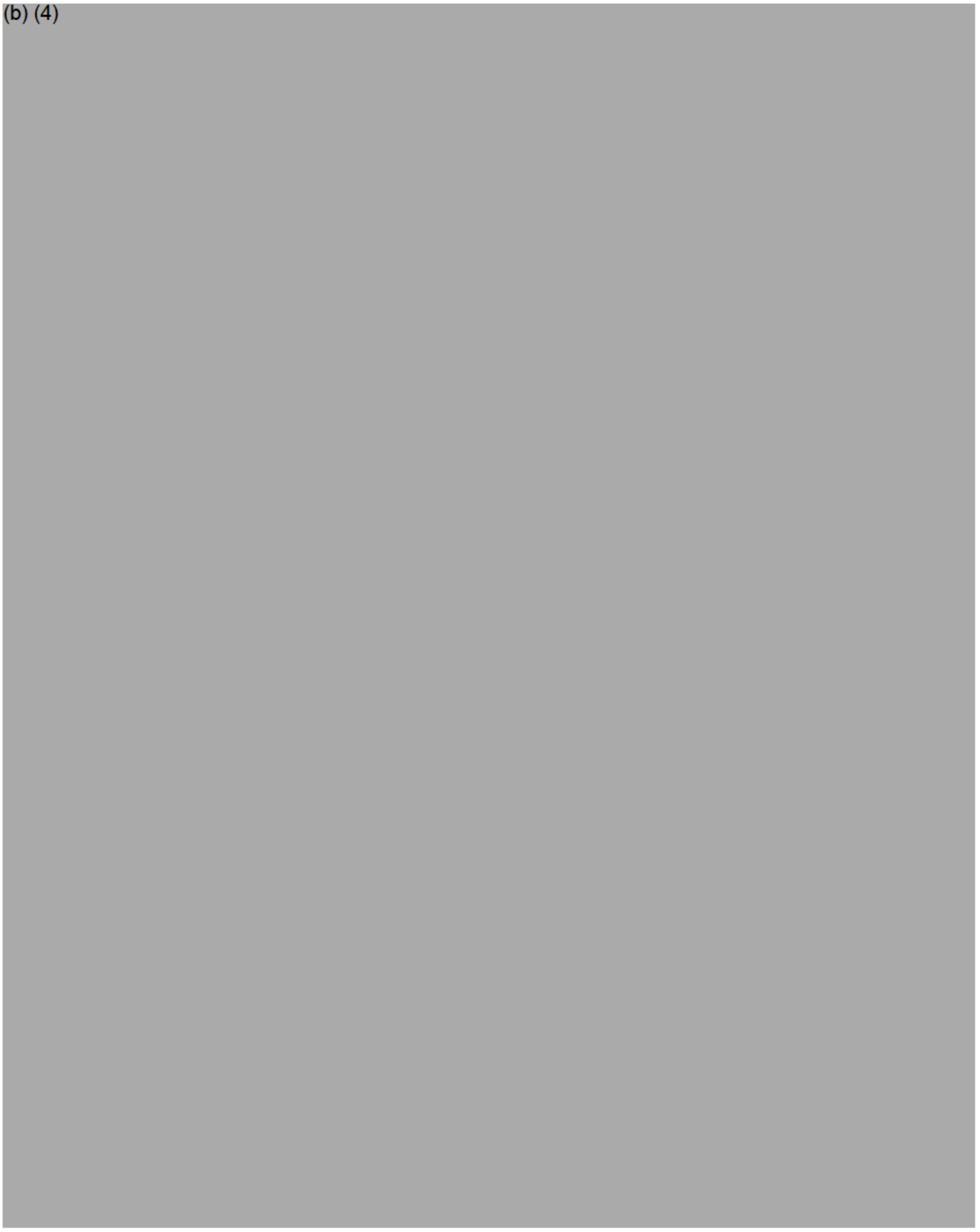
(b) (4)



b. Summary of Material Characterization Testing

(b) (4)

(b) (4)



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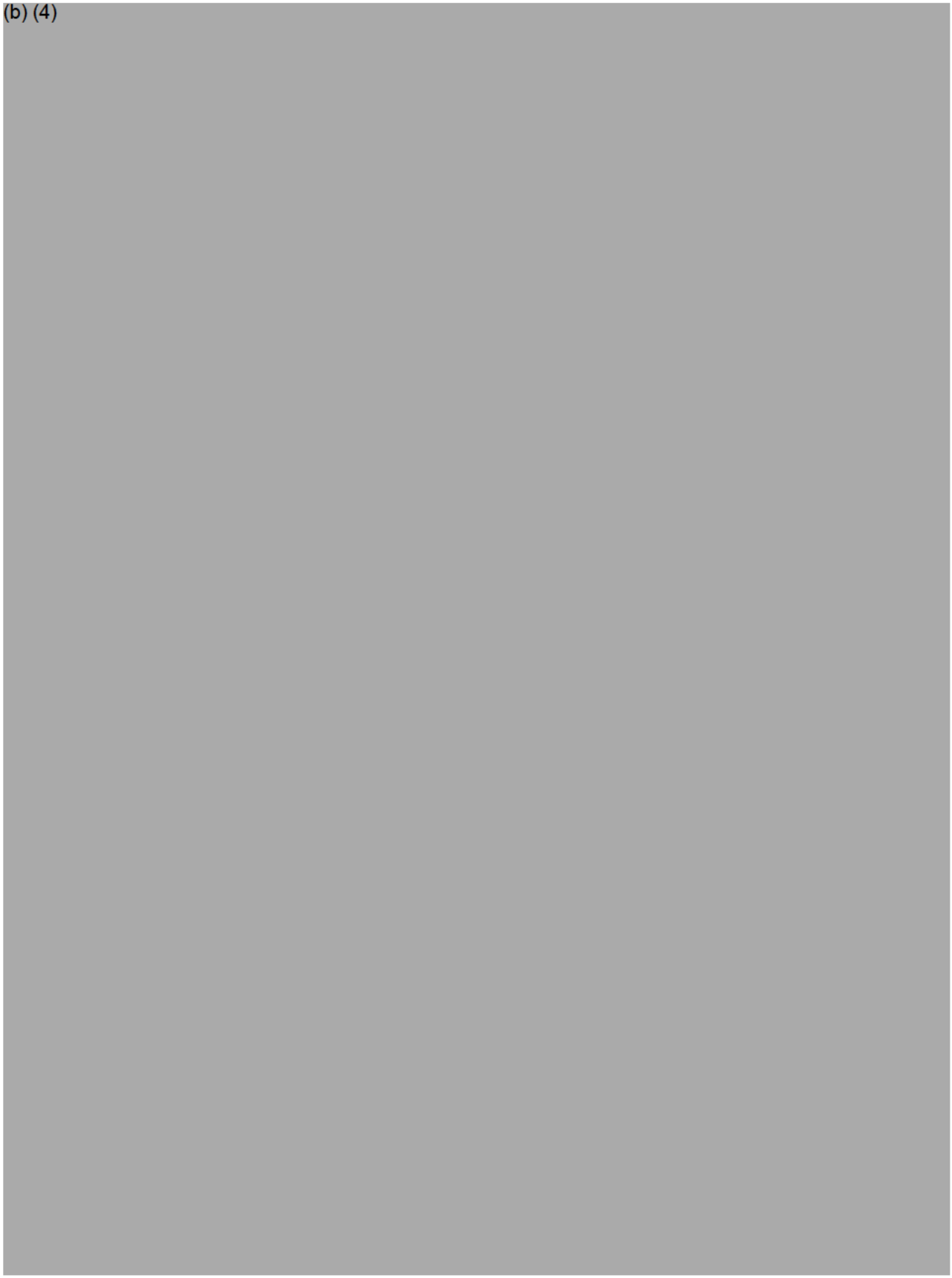

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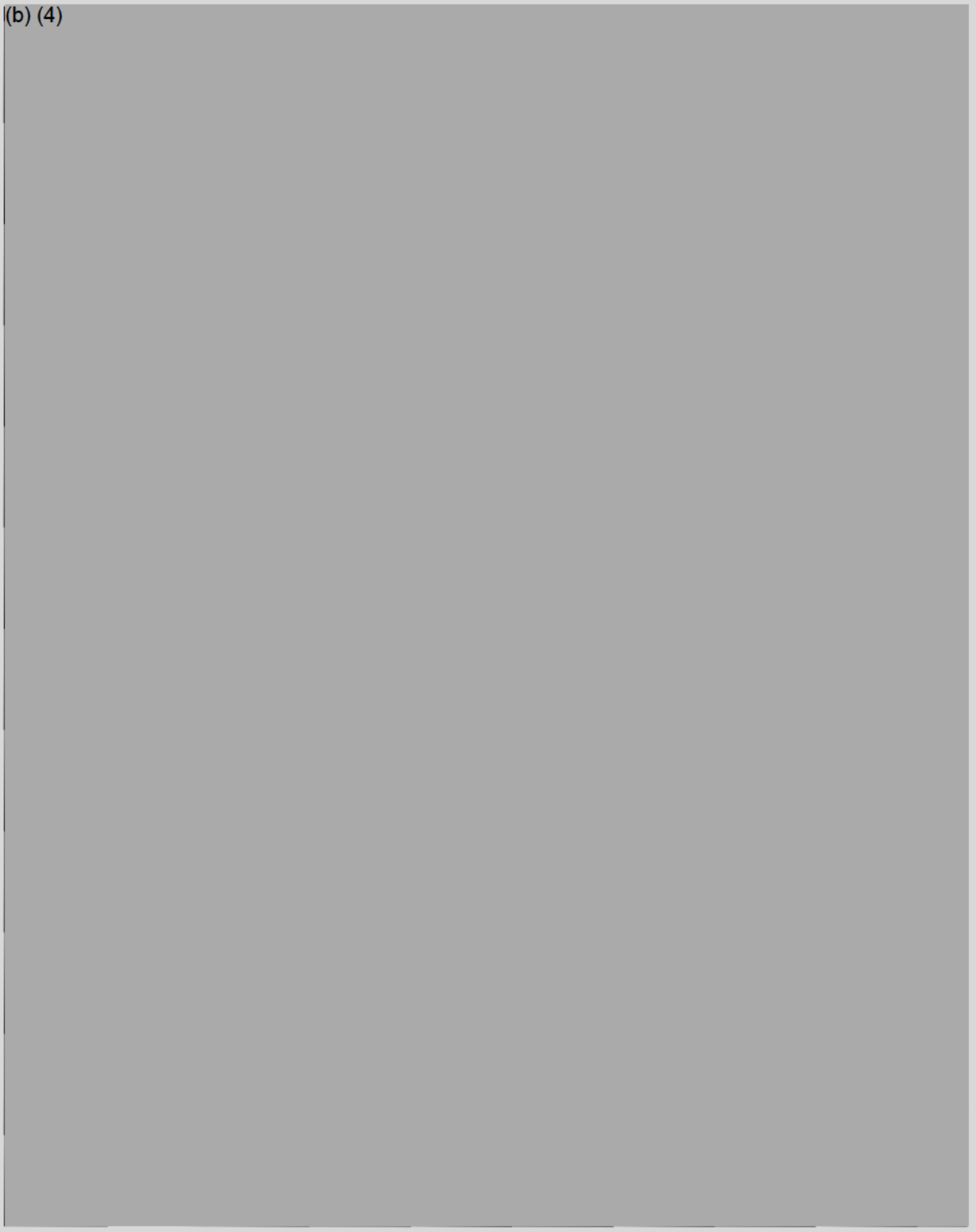


(b) (4)

(b) (4)

Discussion and Conclusion

(b) (4)

40

(b) (4)

ii. Elemental Analysis

(b) (4)

Conclusion

(b) (4)

c. **Summary of Physical Properties Testing**

(b) (4)

[redacted]

i. Physical Characteristics: Density, Porosity, and Dimensional Stability

(b) (4)

[redacted]

ii. *Biological Source Material*

Callos bone void filler contains no biological source material, e.g., neither animal nor human tissue.

d. Summary of Performance Testing

(b) (4)

i. Injection

(b) (4)

ii. Setting Time

(b) (4)

4

(b) (4)

iii. Working time

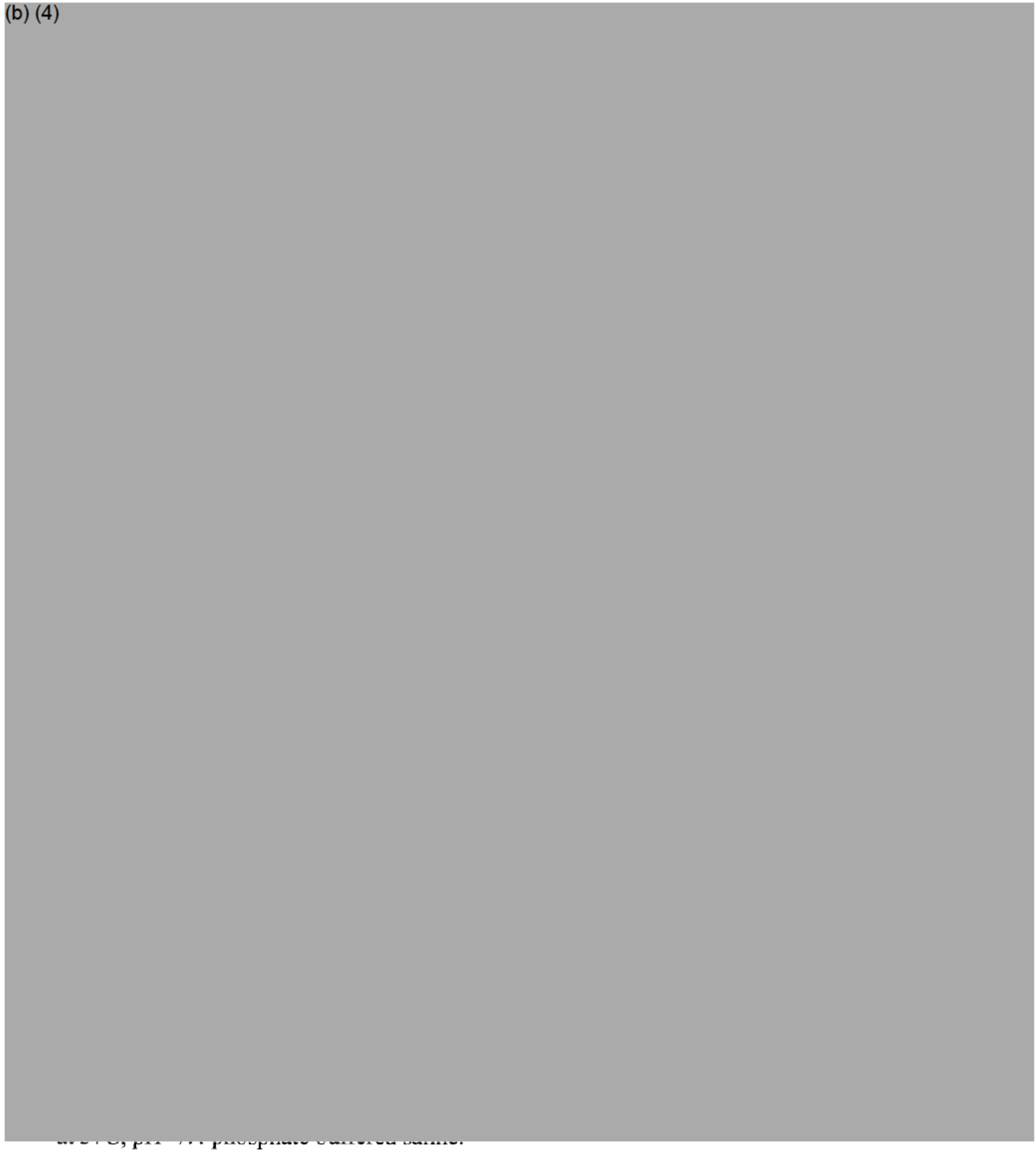
(b) (4)

iv. Temperature and pH measurements

(b) (4)

v. *In vitro* solubility and dissolution testing

(b) (4)

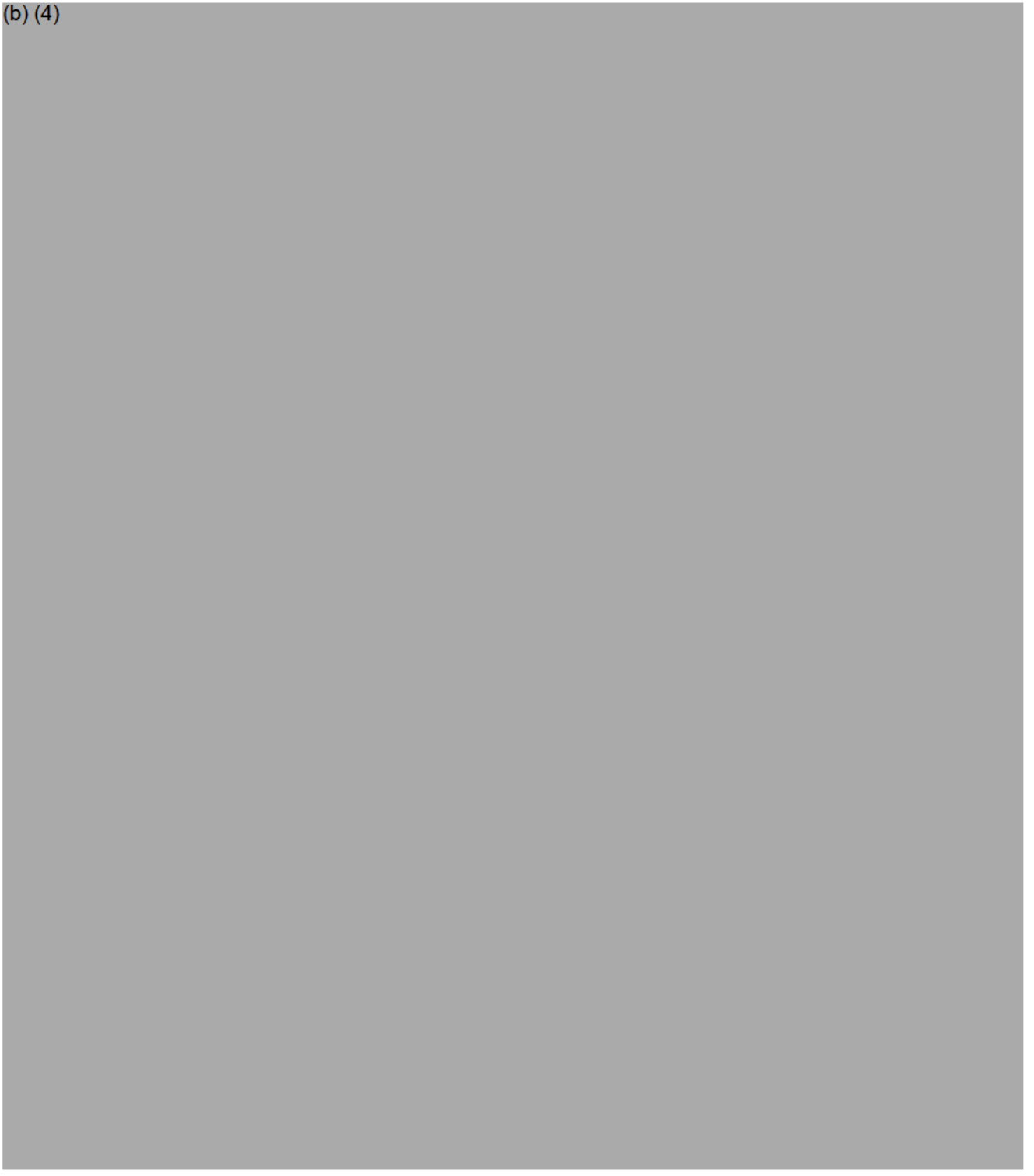


Discussion and Conclusion

(b) (4)

vi. Animal testing: An *in vivo* evaluation of two calcium phosphate bone void fillers

(b) (4)



(b) (4)

a. Surgical Technique

(b) (4)

(b) (4)

(b) (4)

(b) (4)

d. Chemical and Crystallographic Analysis

(b) (4)

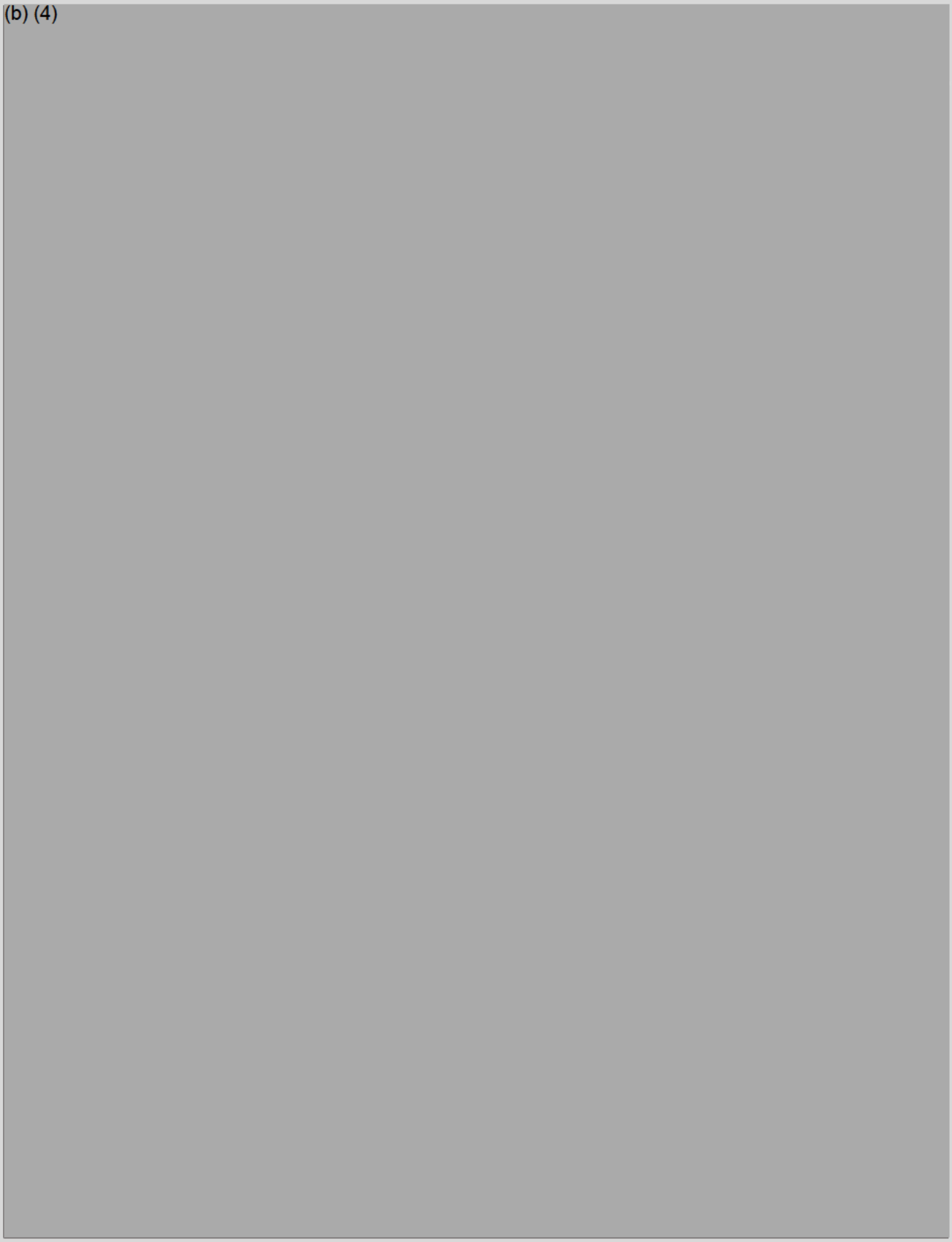
Results

(b) (4)

(b) (4)

(b) (4)

(b) (4)



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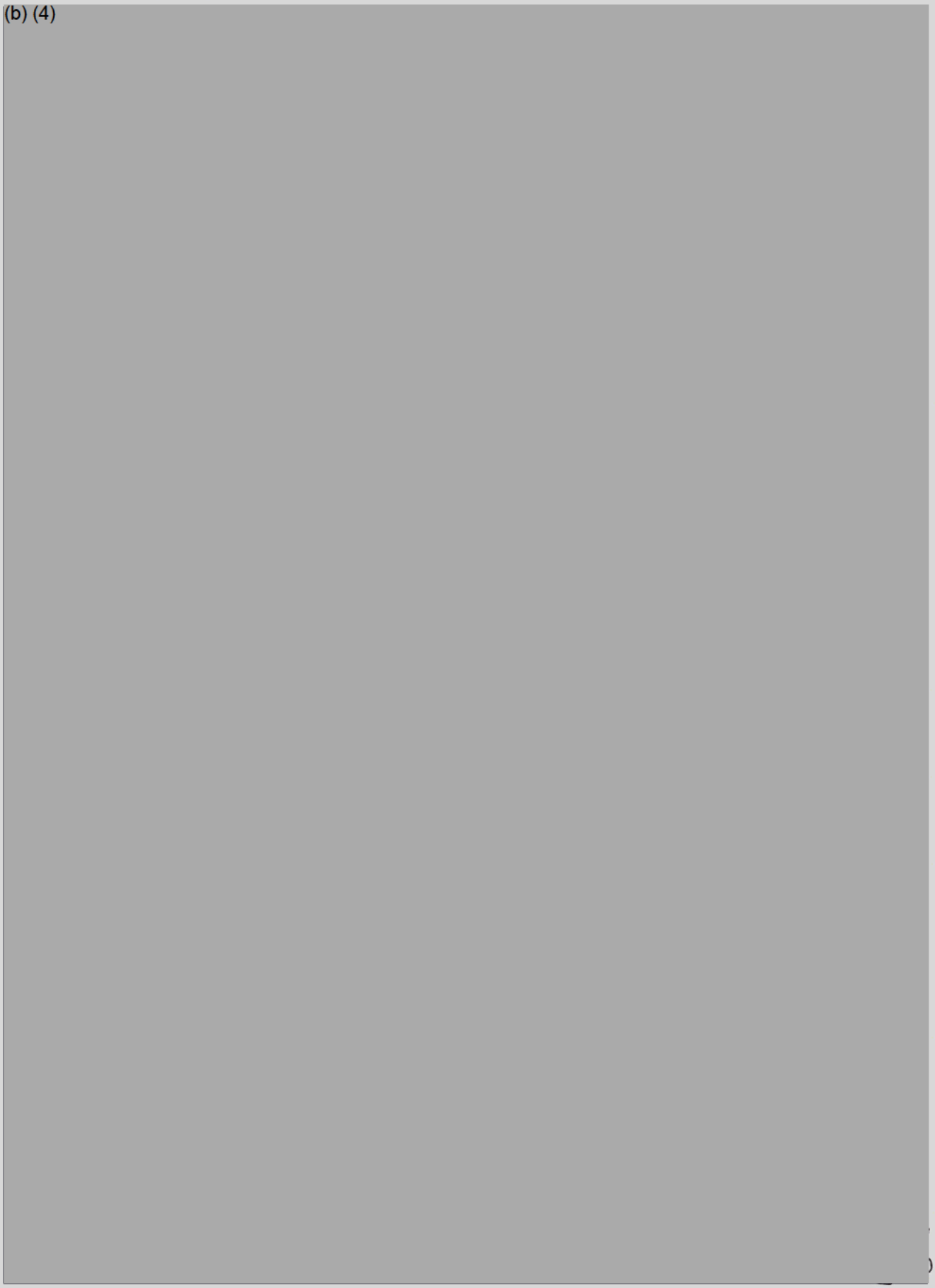
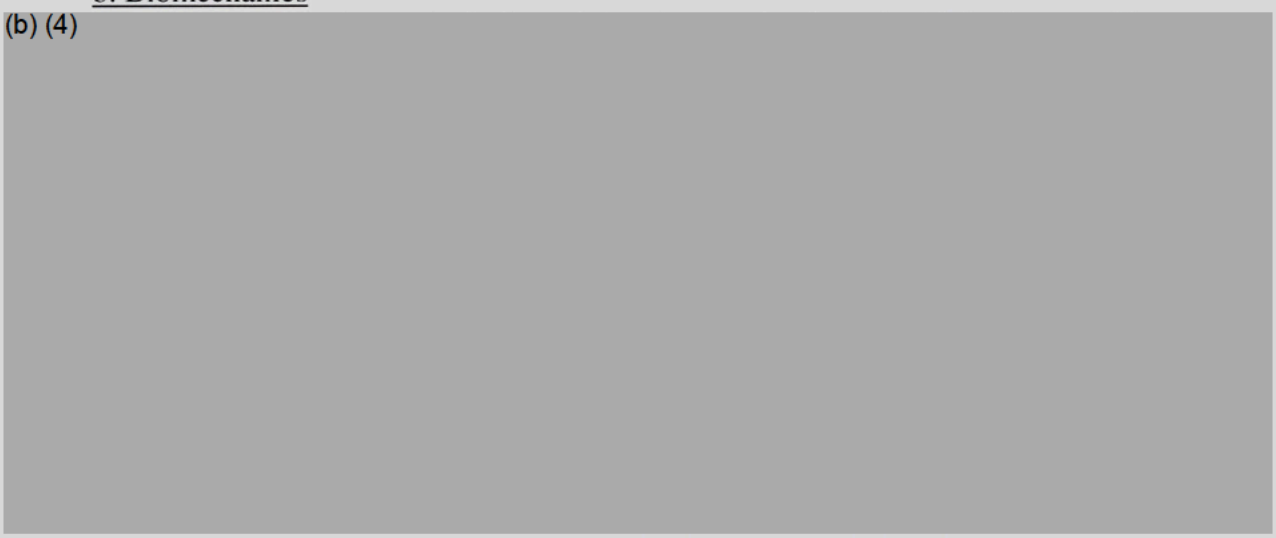


(b) (4)

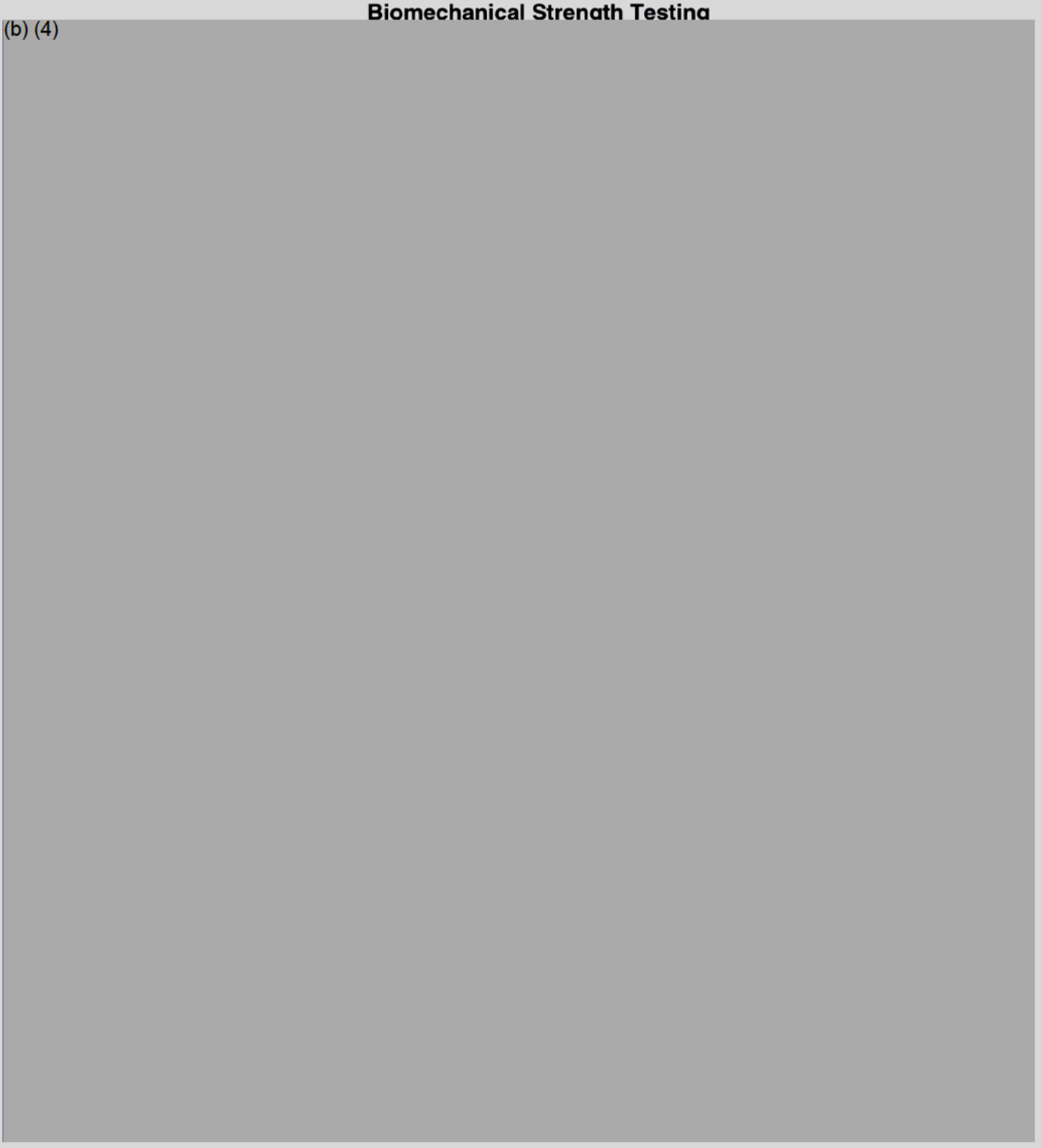
b. Biomechanics

(b) (4)



Biomechanical Strength Testing

(b) (4)



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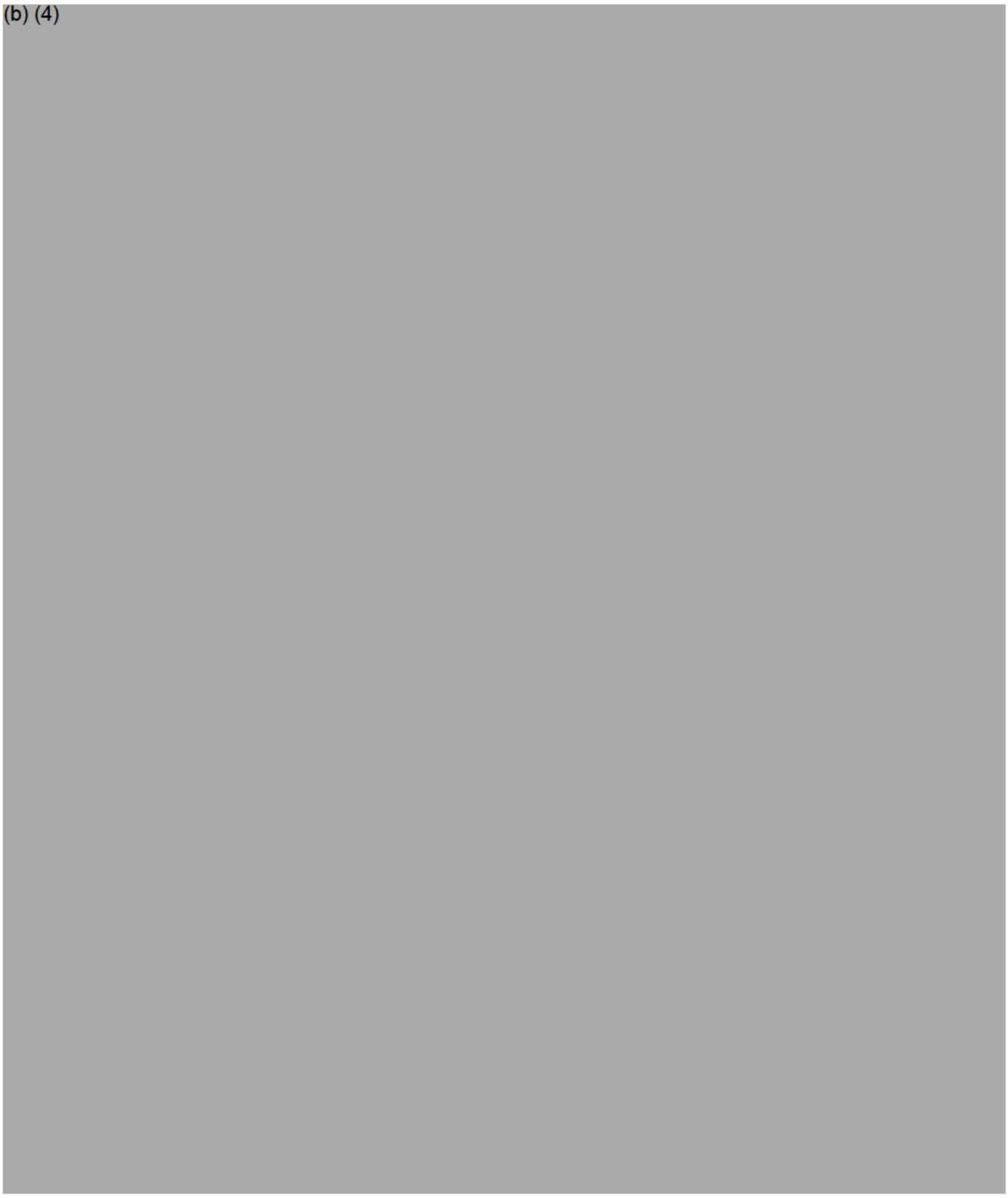
(b) (4)



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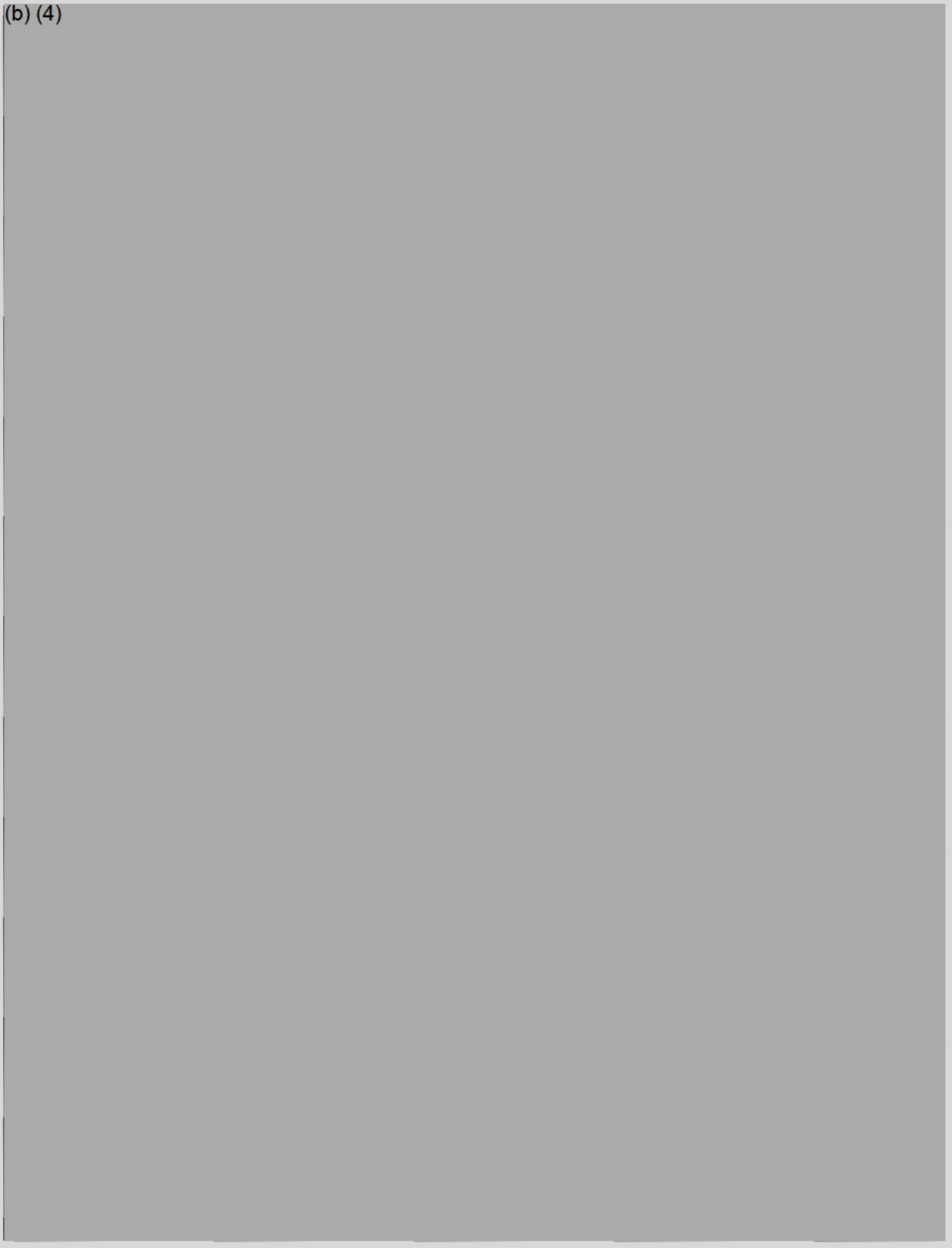

Discussion and Conclusion

(b) (4)

3. Draft IFU

Please see Appendix H for a copy of the draft IFU.

4. Draft labels

Please see Appendix I for sample draft labels for 5 cc Callos Bone Void Filler.

5. Sterilization and shelf life

(b) (4)

(b) (4)

6. Substantial Equivalence Comparison

Table 2: Subject and Predicate Device Comparisons

Substantial Equivalence Comparison	Subject Device Callos Bone Void Filler	Predicate Device Norian SRS Bone Void Filler K011897
Intended Use	(b) (4)	A non-structural bone void filler for osseous defects
Indications for Use		Indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.
Target Population		Individuals with bony defects resulting from surgery or trauma
Design		Self setting calcium phosphate bone void filler which hardens in aqueous environment at 37°C
Components		Package contains one reactant pack with one chamber of powder and one chamber of liquid
Product Preparation		Product is mechanically mixed within a reusable pneumatic mixer
Biocompatibility		Biocompatible
Material Characteristics		
• **Starting Reactants**		Powder: Alpha tricalcium phosphate, Calcium carbonate (Calcite), Monocalcium phosphate monohydrate. Solution: Dilute sodium phosphate.
• **Chemical Composition**		Calcium Phosphate Salt
• **Crystal structure, after hardening**		Hydroxyapatite

	(b) (4)	
• **Calcium to phosphate ratio**		1.67
Physical Properties		
• **Porosity**		~50%
• **Density**		~1.6-1.7 gm/cc
Performance Characteristics		
• **Injectability**		Injectable for 5 minutes
• **Working time**		~2 minutes
• **Setting Time**		~10 minutes
• **pH**		Physiologic
• **Setting reaction temperature**		Isothermic
• **Solubility and Dissolution**		Similar to hydroxyapatite
• **Bone Remodeling**		New bone grows into the graft area via osteoconduction. The material is replaced by cell mediated remodeling tissue response
Sterility		Sterilized by gamma radiation, single use only
Available Sizes		3cc, 5 cc and 10 cc kits
Voluntary Standards Met		Presumed

a. Discussion of similarities and differences

Similarities

(b) (4)

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(b) (4)

Differences and Discussion

(b) (4)

Conclusion

Based on the many similarities and the minimal differences that do not negatively impact the performance of the Callos device, the clinical performance and use of both bone fillers is expected to be essentially indistinguishable. Therefore, Callos bone void filler is substantially equivalent to the predicate device, Norian SRS.

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Appendices

Appendix A—510(k) Truthful and Accurate Statement

1 page

510(k) Truthful and Accurate Statement
[as required by 21 CFR 807.87(j)]

I certify that in my capacity, as the Director of Clinical and Regulatory Affairs for Skeletal Kinetics, LLC, that all data and information submitted in this pre-market notification are truthful and accurate, and that no material facts have been omitted.

Duran Yetkinler 2/20/2003

**SIGNATURE DATE

Duran Yetkinler, M.D., Ph.D.
Director of Clinical and Regulatory Affairs
Skeletal Kinetics, LLC

PREMARKET NOTIFICATION (510(K)) NUMBER

*As required by 21 CFR Section 807.87(j), effective March 14, 1995.
**Must be signed by a responsible person of the firm required to submit the pre-market notification (e.g., not a consultant for the 510(k) submitter.)

Appendix B—510(k) Indications for Use

1 page

510(k) Indications for Use

510(k) Number (if known): _____

Device Name: Callos Bone Void Filler

Indications for use:

Callos Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use_____
(per 21 CFR 801.109)

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

510(k) Number_____

Appendix C—510(k) Summary

2 pages

510(k) Summary

Sponsor: Skeletal Kinetics, LLC
10201 Bubb Road, Cupertino, CA 95014
Contact Person: Duran Yetkinler, M.D., Ph.D.
Phone Number: 408 366 5002
Fax Number: 408 366 1077
Prepared: February 18, 2003

Trade Name: Callos™
Common Name: Bone Graft Substitute
Classification: Unclassified
Product Code: 87 MVQ

Predicate Device: Callos Bone Void Filler is substantially equivalent to Norian SRS Bone Void Filler (K011897).

Device Description: Callos Bone Void Filler is an injectable, moldable and biocompatible bone void filler. Callos Bone Void Filler resorbs and is replaced with bone during the healing process. The 3 cc, 5 cc, and 10 cc Callos Bone Void Filler kits are provided sterile and are for single use only.

Intended Use/Indications for Use: Callos Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Callos Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Technological Characteristics: Similar to the predicate device, Callos Bone Void Filler is an injectable, moldable, biocompatible, resorbable calcium phosphate based material intended for identical indications.

Performance Data: Non-clinical testing included material properties such as density, porosity, dimensional stability, injectability, setting time, working time, pH, and setting temperature. Biocompatibility testing demonstrated that the material is non-cytotoxic, non-systemic toxic, non-mutagenic, non-irritative, non-pyrogenic, and non-sensitizing. Comparative testing with the predicate device showed equivalence in terms of solubility and dissolution rate, X-Ray Diffraction (XRD), Fourier Transform Infrared (FTIR) spectroscopy and elemental analysis. Animal testing demonstrated substantial equivalence to the predicate device following *in vivo* implantation. Histological, chemical, crystallographical, and mechanical analyses showed substantial equivalence.

Basis for Substantial Equivalence: The Callos Bone Void Filler has the same intended use, identical indications, and very similar technological characteristics as the predicate device. Any minor technological differences between Callos Bone Void Filler and its predicate device do not raise any new issues of safety or effectiveness.

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Functional, biocompatibility, and animal testing results show that the Callos Bone Void Filler is as safe and effective as the predicate device. Thus, the Callos Bone Void Filler is substantially equivalent.

Appendix D—Biocompatibility Complete Test Report

1. MEM Elution Test: *In vitro* cytotoxicity:	8 pages
2. *Salmonella Typhimurium* Reverse Mutation Assay: AMES Test	17 pages
3. Irritation: Intracutaneous reactivity (ISO)	9 pages
4. Systemic Toxicity: ISO/USP Systemic Injection	8 pages
5. Sensitization: ISO Magnusson Klingman Method (2 extracts)	13 pages

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

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(b)(4) Test Data

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Appendix E—Material Characterization Complete Test Report

Title: **Chemical and Crystallographic analysis:** (b) (4)

Investigators: Dave Delaney, Brent R Constantz PhD

Approval: Duran N Yetkinler MD, PhD

Facility: Skeletal Kinetics, LLC
10211 Bubb Road
Cupertino, CA 95014-4166

Testing: 18-January-03

Final Report: 31-January-03

Objective

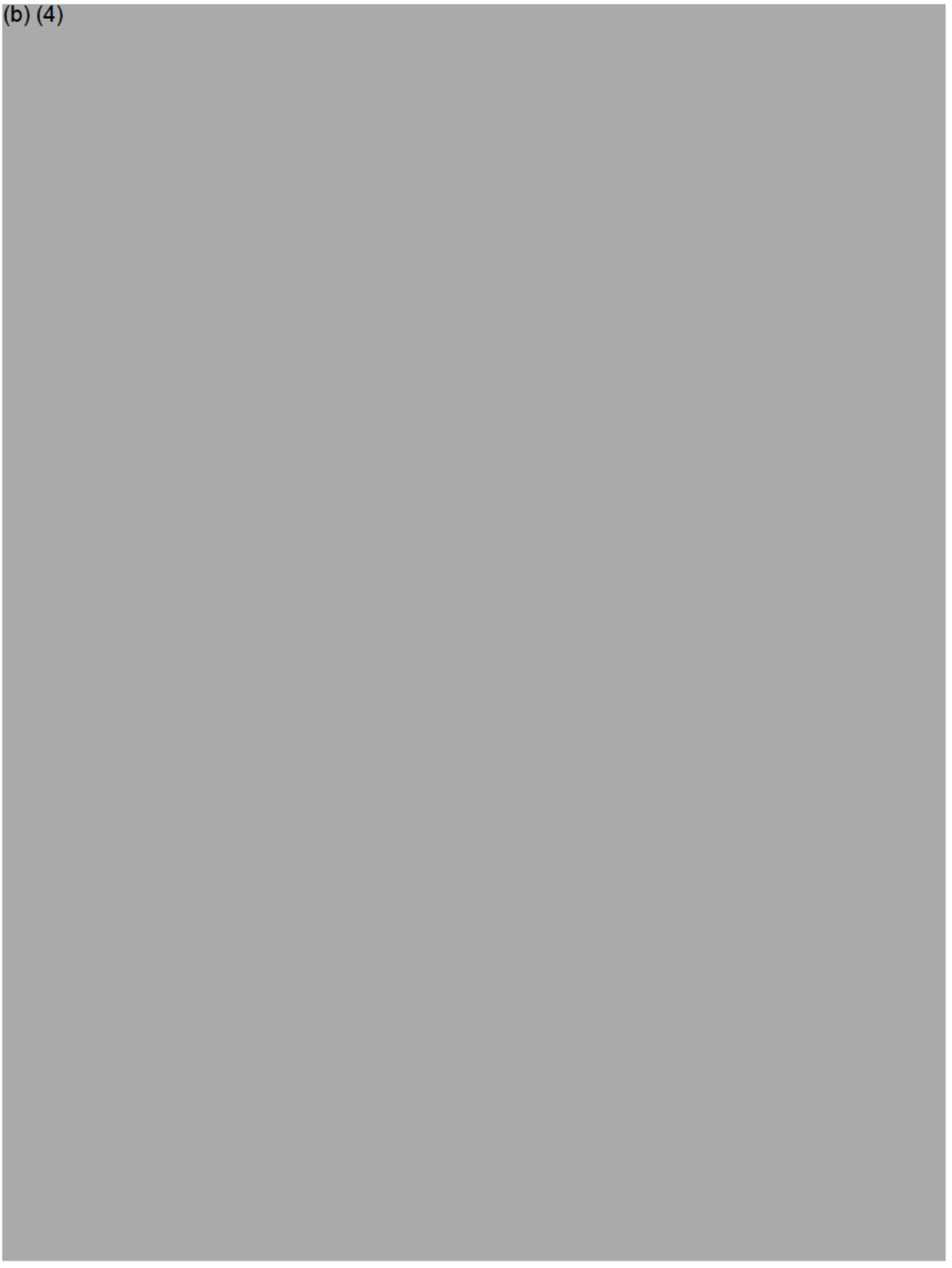
(b) (4)

(b) (4)

Results

(b) (4)

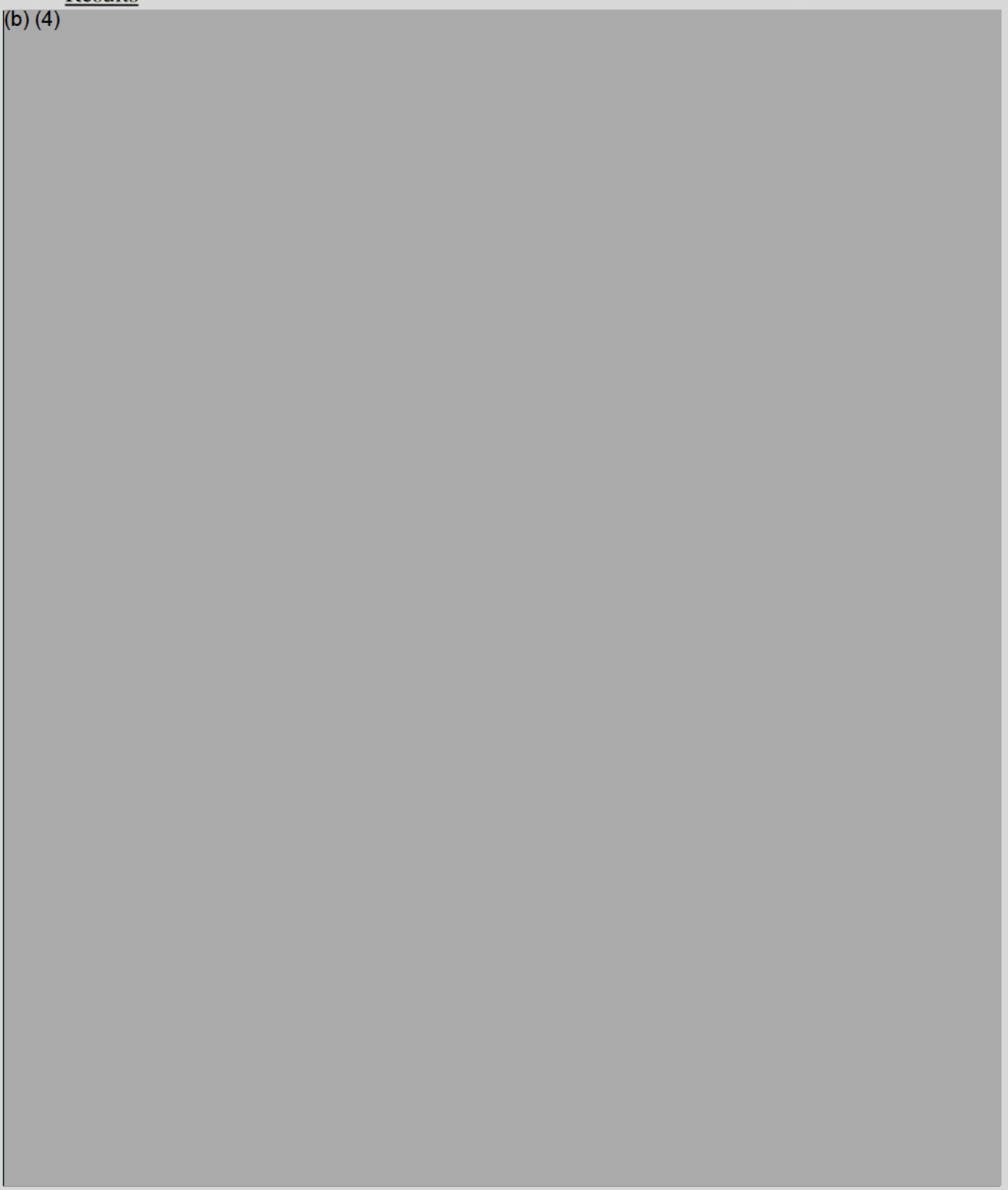
(b) (4)



(b) (4)

Results

(b) (4)



(b) (4)

(b) (4)

Discussion and Conclusion

(b) (4)

(b) (4)

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

Appendix F—Physical Properties Complete Test Report

Physical Characteristics: Density, Porosity, and Dimensional Stability 2 pages

Title: Physical Characteristics: Density, Porosity, and Dimensional Stability

Investigator: David Delaney

Approval: Duran N Yetkinler MD, PhD

Facility: Skeletal Kinetics
10201 Bubb Rd
Cupertino CA 95014

Objective (b) (4)

Materials
(b) (4)

Density and Porosity Procedure
(b) (4)

Dimensional Stability Procedure
(b) (4)

Results
(b) (4)

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(b) (4)

(b) (4)

(b) (4)

(b) (4)

Discussion and Conclusions

(b) (4)

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Appendix G—Performance Complete Test Report

Title: **Injection Testing of Callos Bone Void Filler**

Investigators: Dave Delaney, Brent R Constantz PhD

Approval: Duran N Yetkinler MD, PhD

Facility: Skeletal Kinetics, LLC
10211 Bubb Road
Cupertino, CA 95014-4166

Testing: 18-January-03

Final Report: 31-January-03

(b) (4)

(b) (4)

Results

(b) (4)

Discussion and Conclusion

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(b) (4)

Table 1: Injection Test Data

(b) (4)

References

ASTM F 451-86

150

Title: **Initiation of Setting Testing of Callos Bone Void Filler**

Investigators: Dave Delaney, Brent R Constantz PhD

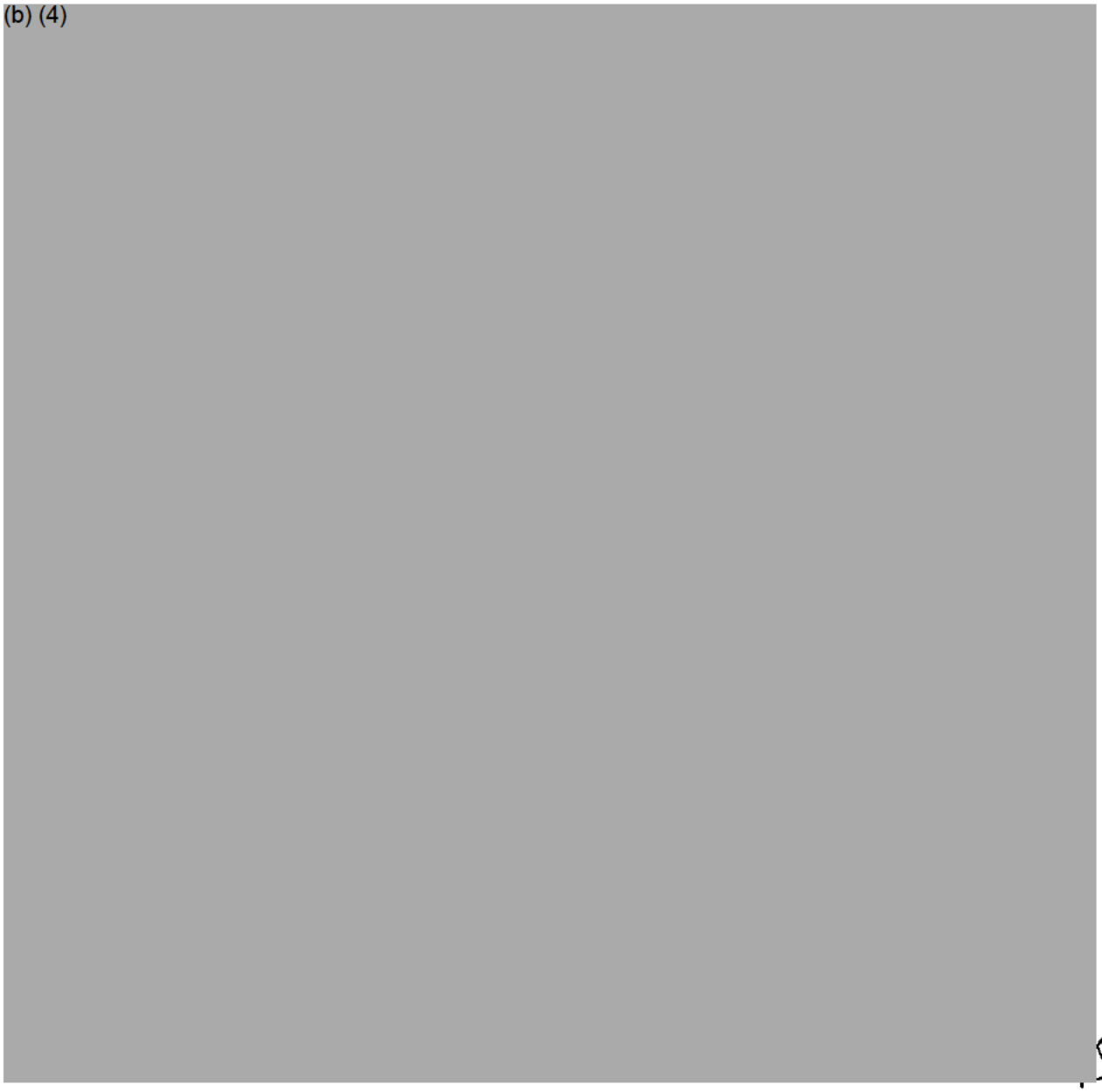
Approval: Duran N Yetkinler MD PhD

Facility: Skeletal Kinetics, LLC
10211 Bubb Road
Cupertino, CA 95014

Testing: 22-January-03

Final Report: 31-January-03

(b) (4)



(b) (4)

Results

(b) (4)

Conclusions

(b) (4)

References

ASTM C403/C403M-99
ASTM C266-99

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Table 1: (b) (4)

(b) (4)

Title: **Working Time Testing of Callos Bone Void Filler**

Investigators: David Delaney, Brent R Constantz PhD

Approval: Duran N Yetkinler MD PhD

Facility: Skeletal Kinetics, LLC
10211 Bubb Road
Cupertino, CA 95014

Testing: 20-January-03

Final Report: 31-January-03

(b) (4)

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Procedure

(b) (4)

Results

(b) (4)

Conclusions

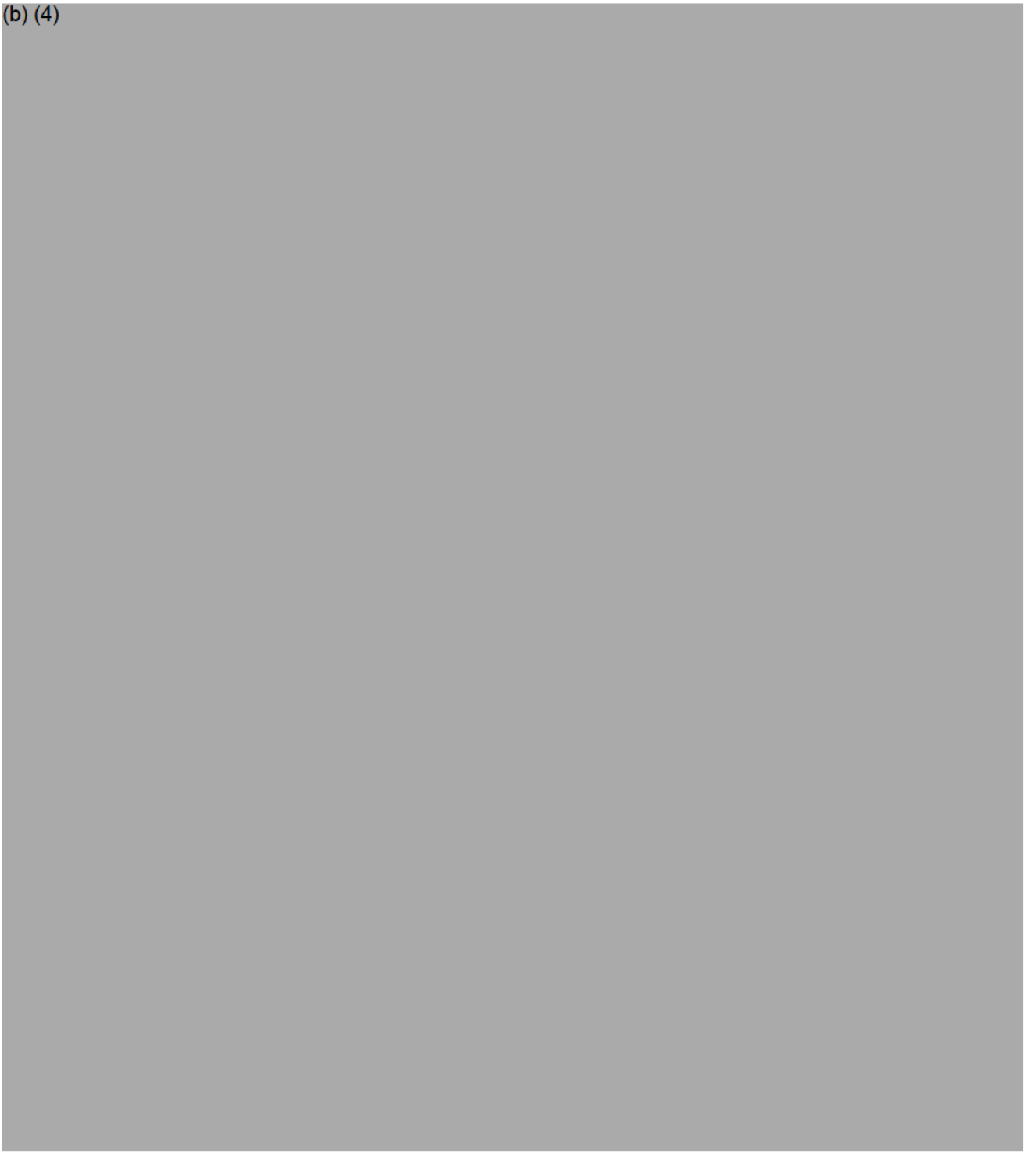
(b) (4)

References

ASTM C403/C403M-99
ASTM C266-99

155

(b) (4)



Title: **Temperature and pH Testing of Callos Bone Void Filler**

Investigator: David Delaney

Approval: Duran N Yetkinler MD, PhD

Facility: Skeletal Kinetics
10201 Bubb Rd
Cupertino CA 95014

(b) (4)

Results

(b) (4)

(b) (4)

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Discussion and Conclusion

(b) (4)

Title: ***In vitro* Solubility and Dissolution Rate**

Investigators: Dave Delaney, Brent R Constantz PhD

Approval: Duran N Yetkinler MD, PhD

Facility: Skeletal Kinetics, LLC
10211 Bubb Road
Cupertino, CA 95014-4166

Testing: 18-January-03

Final Report: 31-January-03

(b) (4)

(b) (4)

Results

(b) (4)

(b) (4)

Discussion and Conclusions

(b) (4)

(b) (4)

AN *IN VIVO* EVALUATION OF TWO CALCIUM PHOSPHATE BONE VOID FILLERS

PURPOSE

This study evaluated the biocompatibility, bone resorption, formation, and biomechanical properties of the implanted regions containing Callos and Norian SRS bone void fillers. Histological, mechanical and crystallographic analyses were performed following implantation in the rabbit femur. Callos™ (Skeletal Kinetics, LLC, Cupertino, CA) and Norian SRS (Synthes Corp., Paoli, PA) were used in this paired design study.

METHODS

(b) (4)

Table 1. Flow chart of the experimental design for the study.

(b) (4)

Surgical Technique

(b) (4)

165

(b) (4)

Histological Analysis

(b) (4)

166

(b) (4)

Biomechanical Testing

(b) (4)

Chemical and Crystallographic Analysis

(b) (4)

Statistical Analysis

(b) (4)

RESULTS

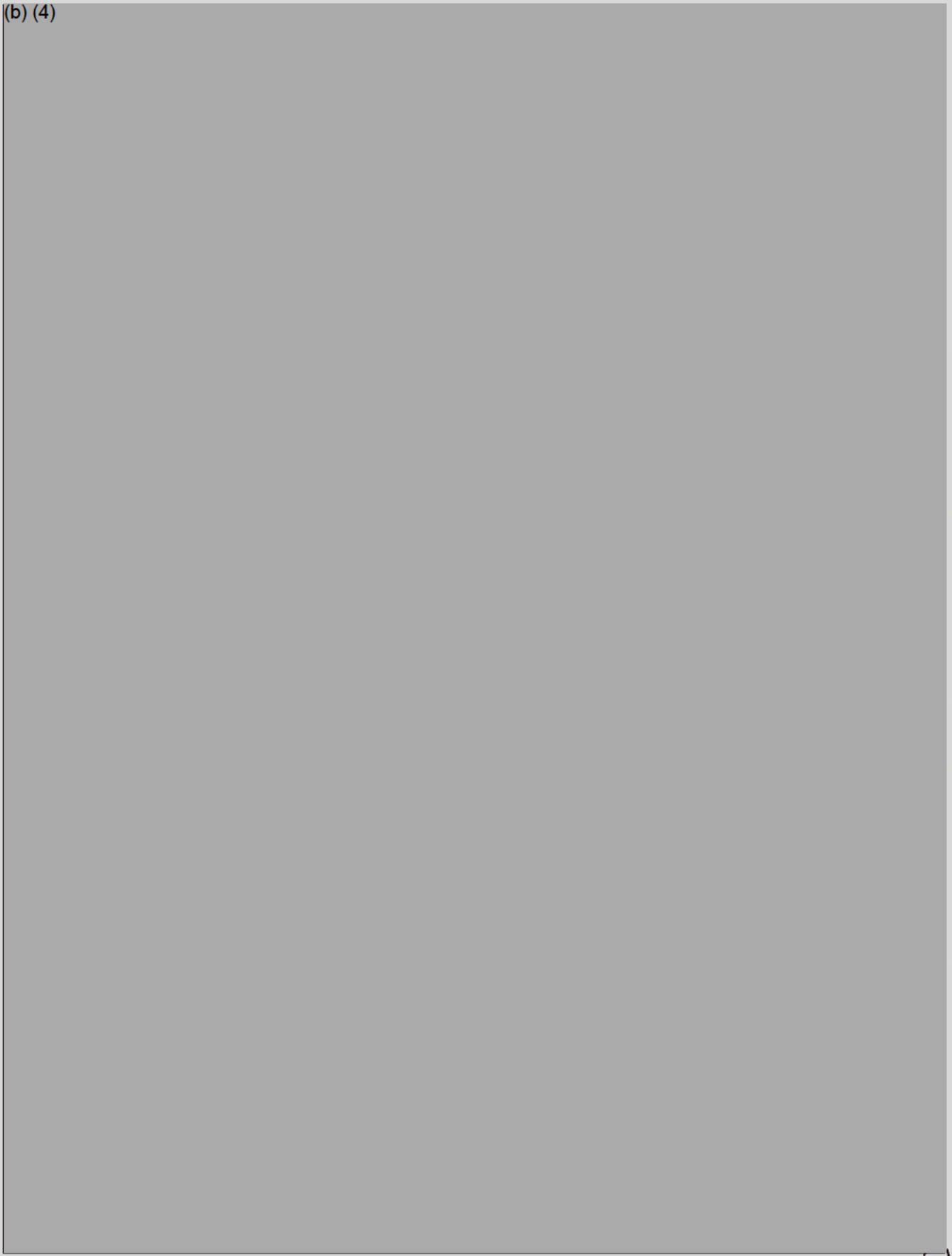
Histology

(b) (4)

(b) (4)

(b) (4)

(b) (4)



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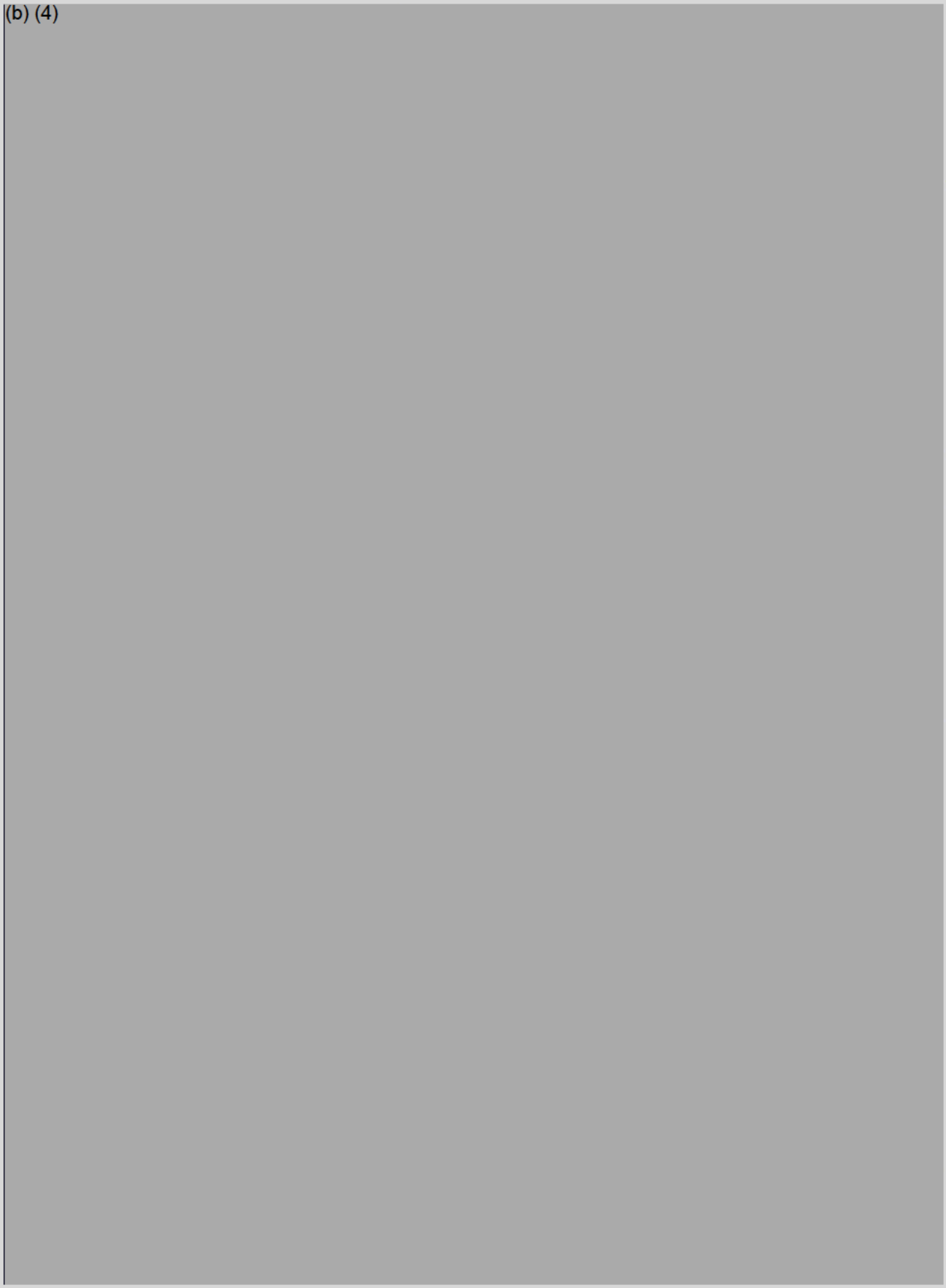
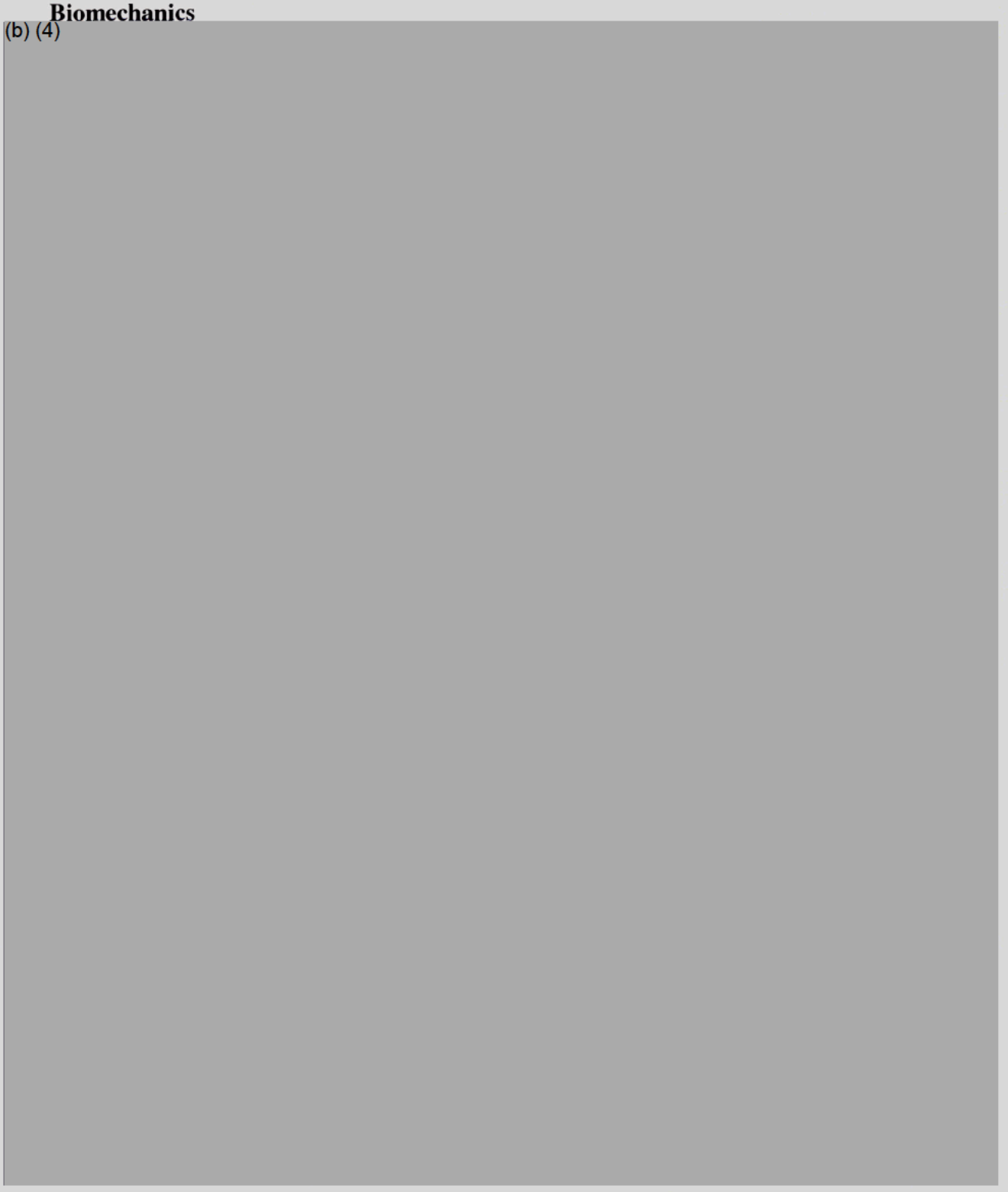


(b) (4)

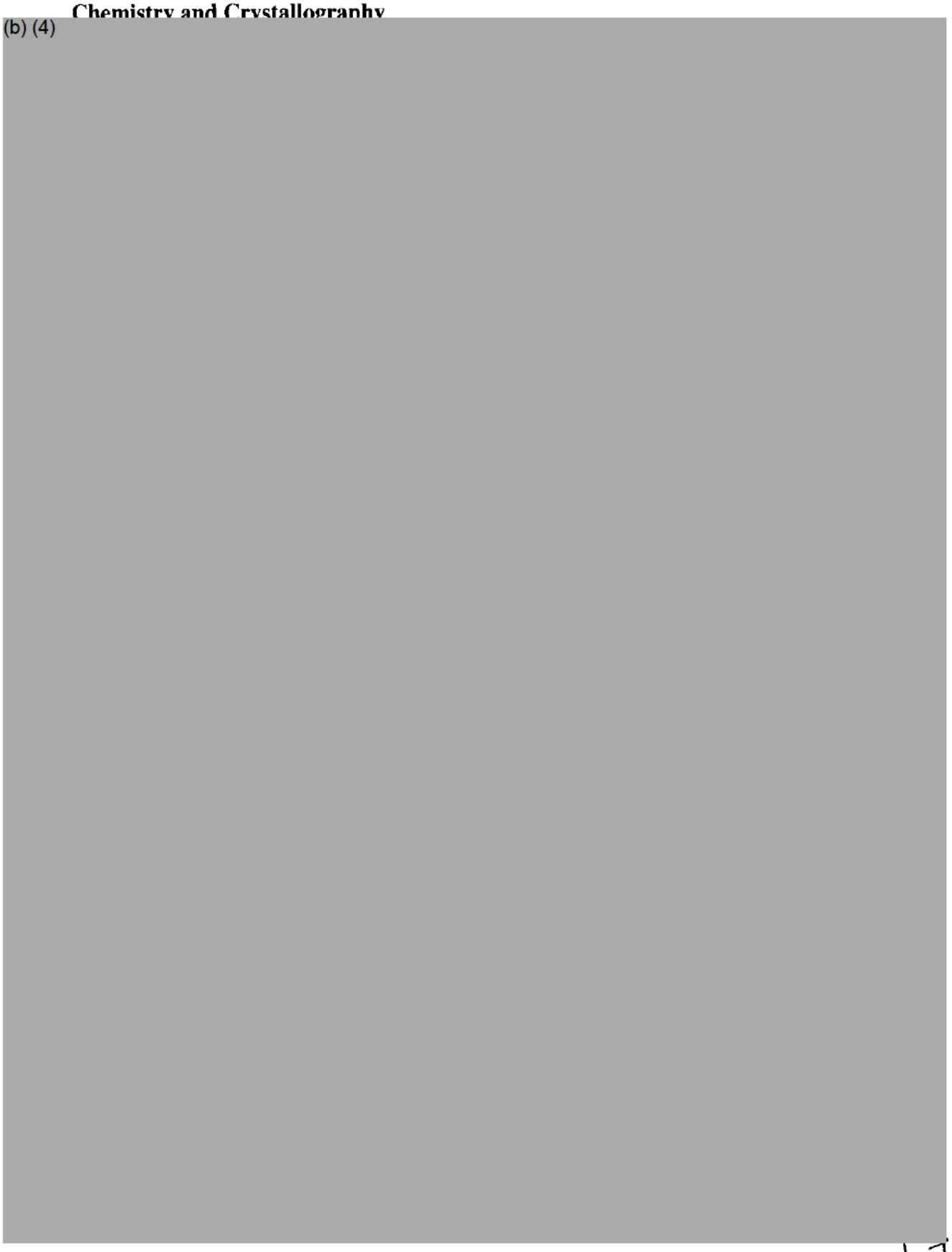
Biomechanics

(b) (4)



Chemistry and Crystallography

(b) (4)



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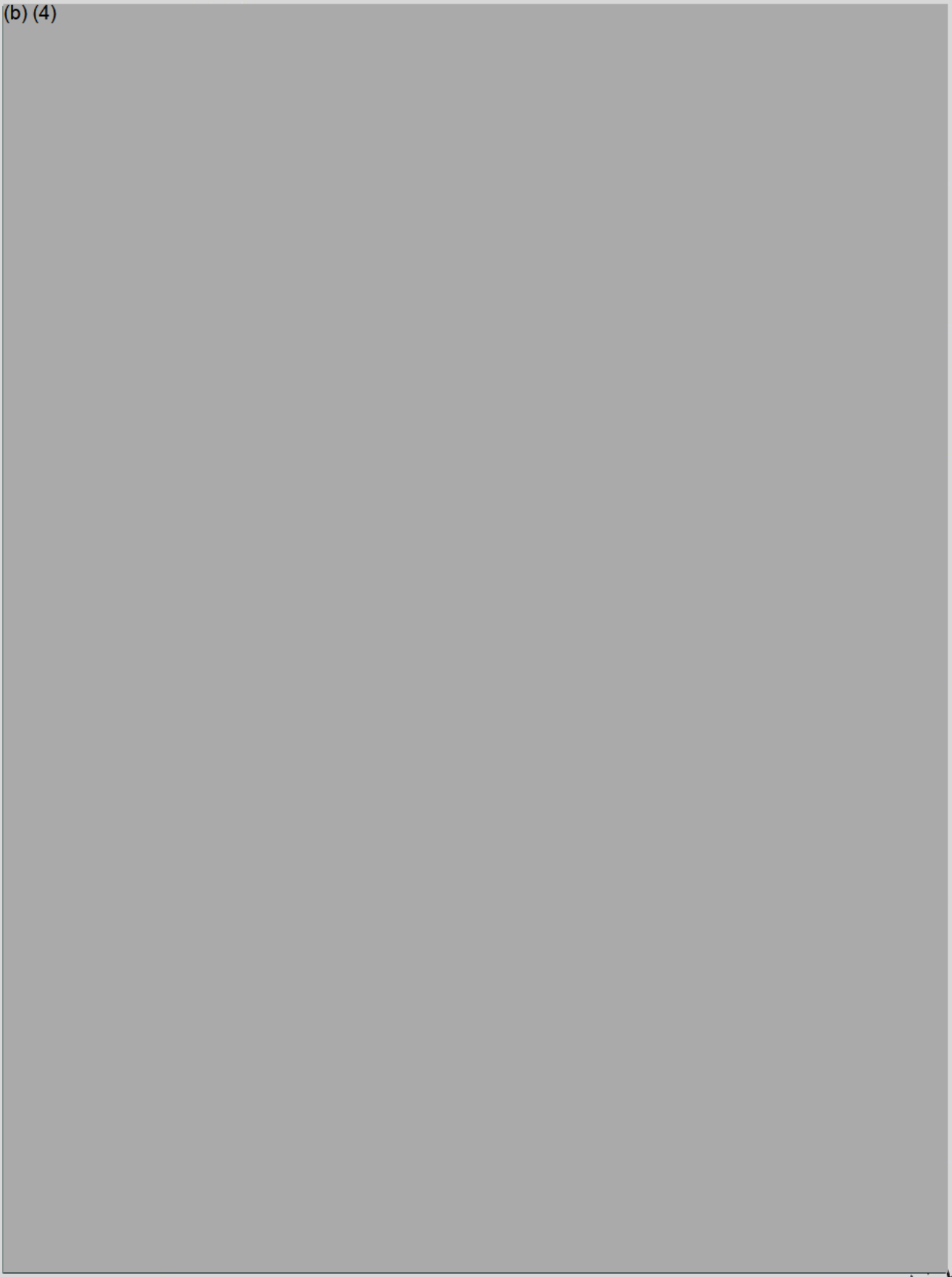


DISCUSSION AND CONCLUSION

(b) (4)

REFERENCES

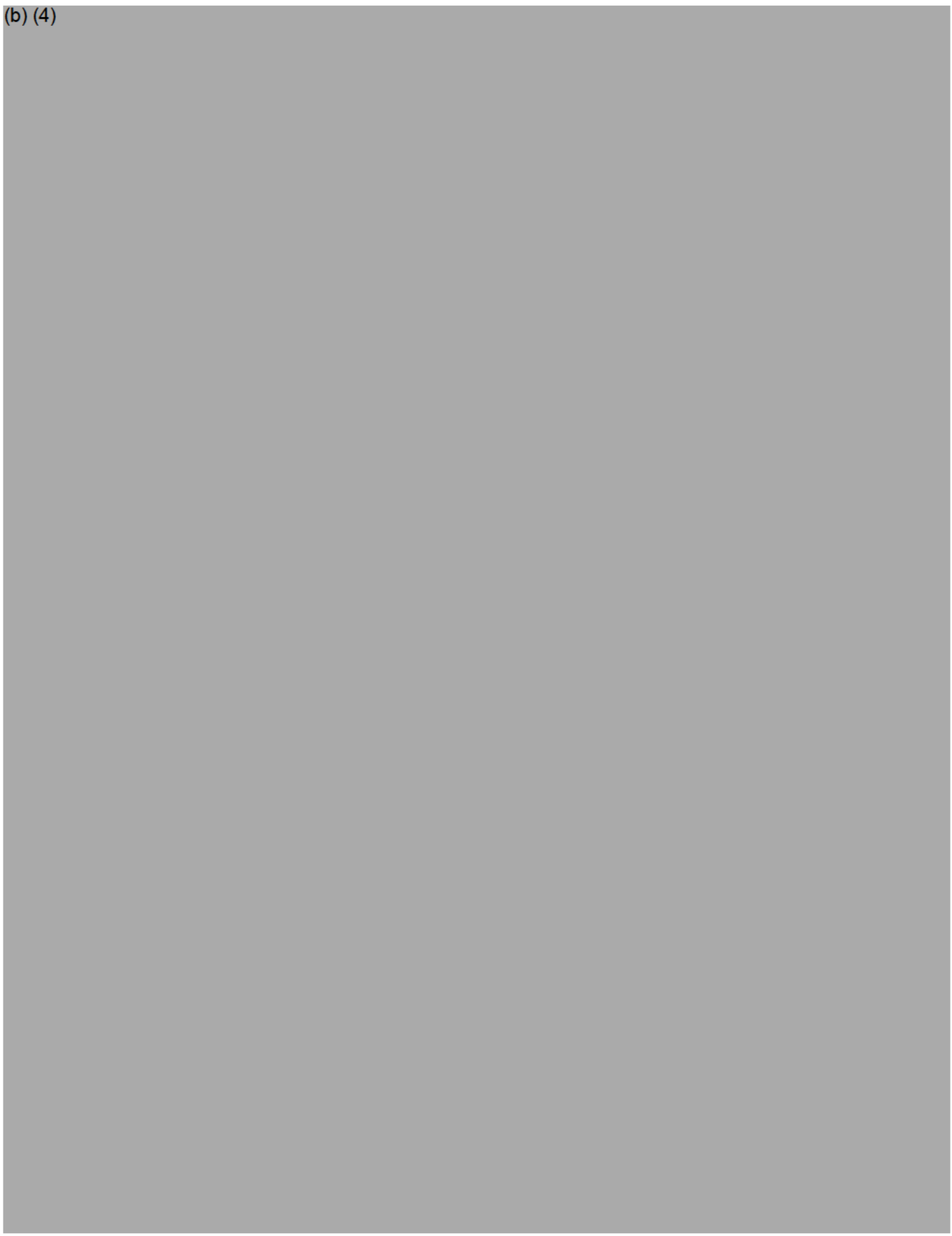
(b) (4)

Appendix H—Draft IFU

3 pages

Draft IFU

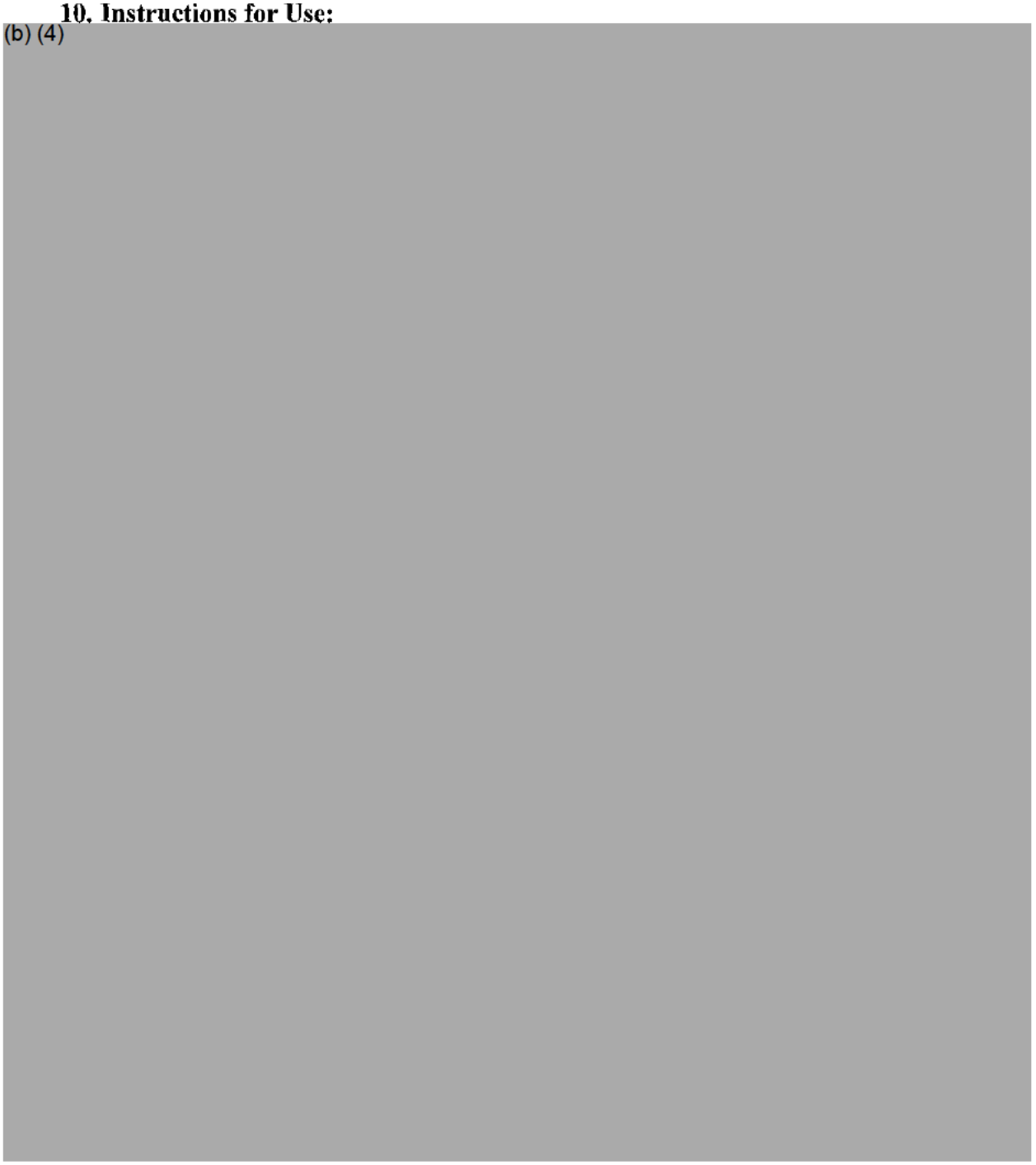
(b) (4)



(b) (4)

10. Instructions for Use:

(b) (4)



Appendix I—Draft package labels

2 pages

Draft package labels

(b) (4)

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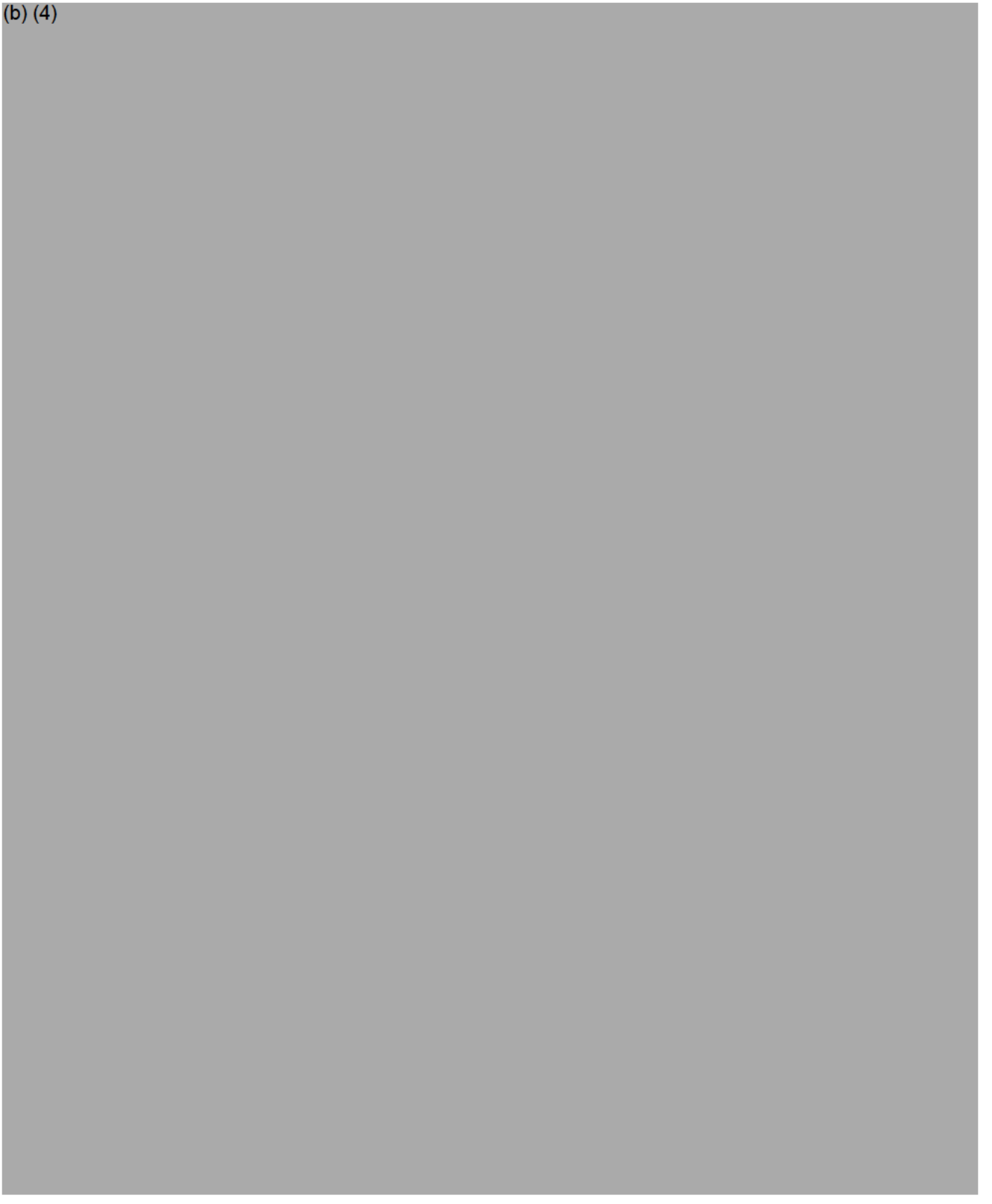
(b) (4)



Appendix J—Sterilization Validation Protocol

8 pages

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

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(b)(4) Test Data

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Vidmi Sloan

Subject: 510(k) Number K030554

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

- ☒ A 510(k) summary OR ☐ A 510(k) statement
- ☐ The required certification and summary for class III devices
- ☒ The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source ☐ YES ☒ NO COMBINATION: N

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 day

Predicate Product Code with class: MQV unclassified

Additional Product Code(s) with panel (optional):

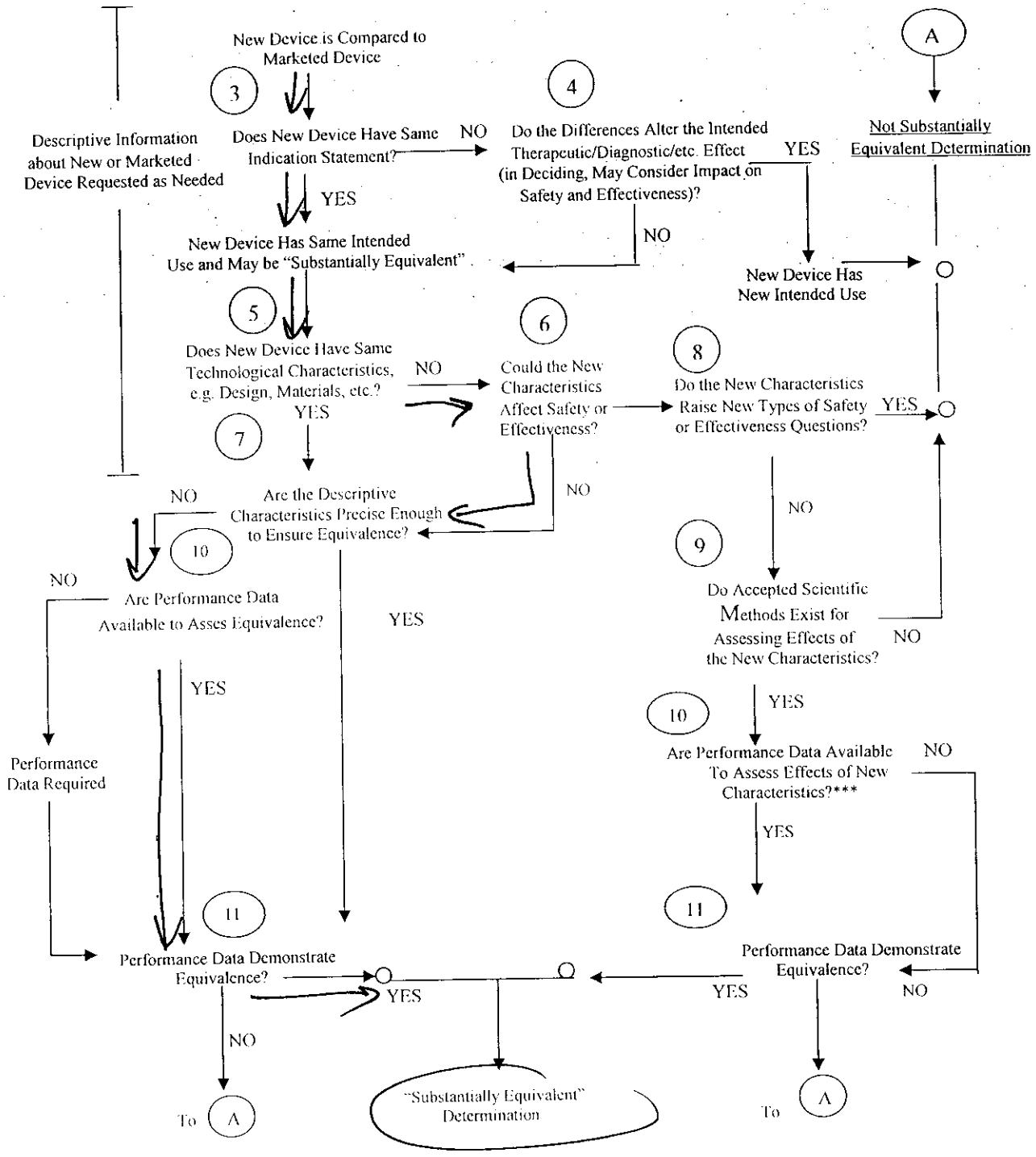
Review: (Branch Chief) REDB (Branch Code) 5/19/03 (Date)

Final Review: Mark N Melkerson (Division Director) 5/19/03 (Date)

Revised:8/17/99

4

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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"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K030554

Date: 5/16/03

Reviewer: Nadine Y. Sloan

Division/Branch: DGRND/REDB

Device Name: Callos Bone Void Filler

Product To Which Compared (510(K) Number If Known: Norian SRS (K011897)

		YES	NO	
1.	Is Product A Device	✓		If **NO** = Stop
2.	Is Device Subject To 510(k)?	✓		If **NO** = Stop
3.	Same Indication Statement?	✓		If **YES** = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues Safety Or Effectiveness?			If **YES** = Stop **NE**
5.	Same Technological Characteristics?		✓	If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?		✓	If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?		✓	If **NO** = Go To 10 If **YES** = Stop **SE**
8.	New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10.	Performance Data Available?	✓		If **NO** = Request Data
11.	Data Demonstrate Equivalence?	✓		Final Decision: **SE**

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. **Intended Use:** Identical to predicate device.

Callos Bone Void filler is indicated to fill bony voids or gaps of the skeletal system (i.e., extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to bone. Callos Bone Void filler is indicated only for boney voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

2. **Device Description:** Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement.

Subject Device: (b) (4)

Predicate Device: Norian is a calcium phosphate based bone cement which hardens in situ to form a carbonated apatite. The pre-mixed Norian SRS Bone Void Filler is comprised of monocalcium phosphate, monohydrate [MCPM, ($Ca(H_2P0_4)_2.H_20$)], a-tricalcium phosphate [TCP, $Ca_3(P0_4)_2$], and calcium carbonate (CC, $CaCO_3$), to which a sodium phosphate solution ($NaHPO_4.7H_20$) is added to form a paste. The device is injected into the void space where it hardens in approximately 10 minutes. Norian SRS Bone Void Filler is slowly resorbed/remodeled. See attached summary table provided by the sponsor.

Is the device life-supporting or life sustaining? *No.*
Is the device implanted (short-term or long-term)? Yes (long term implant that slowly resorbs over a period of years)
Does the device design use software? *NA*
Is the device sterile? *Yes.*
Is the device for single use? *Yes.*
Is the device over-the-counter or prescription use? *Prescription use.*
Does the device contain drug or biological product as a component? *No.*
Is this device a kit? *No (not in the regulatory sense, although it is provided with components necessary to mix materials to form intended paste).*

Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

(b) (4)

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(b) (4)

[redacted]

comparison table provided by sponsor for results).

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device: NA
2. Explain why not subject to 510(k): NA
3. How does the new indication differ from the predicate device's indication: NA
4. Explain why there is or is not a new effect or safety or effectiveness issue: NA
5. **Describe the new technological characteristics:**

   Different starting materials are used, as specified above.

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

(b) (4)

[redacted]

7. **Explain how descriptive characteristics are not precise enough:**

(b) (4)

[redacted]

11. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:**

8

(b) (4)

[redacted]

ATTACH ADDITIONAL SUPPORTING INFORMATION

See attached SE comparison table and discussion (taken directly from the 510(k)).

INSTRUCTIONS FOR USE

The labeling has been revised to be consistent with the cautions and precautions section for the predicate device. (Not all of the cautions/precautions for the predicate device were incorporated into the Callos labeling since not all of the cautions applied to devices of this type.) The final draft labeling was reviewed in comparison to predicate device and was determined to be acceptable. In addition, the instructions are consistent with how the device was studied (in vitro and in vivo).

RECOMMENDATION:

Substantially equivalent to Norian Bone Void Filler (K011897), unclassified.

Nadine Y. Sloan
Callos.SE.dec

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6. Substantial Equivalence Comparison

Table 2: Subject and Predicate Device Comparisons

Substantial Equivalence Comparison	Subject Device Callos Bone Void Filler	Predicate Device Norian SRS Bone Void Filler K011897
Intended Use	(b) (4)	A non-structural bone void filler for osseous defects
Indications for Use		Indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.
Target Population		Individuals with bony defects resulting from surgery or trauma
Design		Self setting calcium phosphate bone void filler which hardens in aqueous environment at 37°C
Components		Package contains one reactant pack with one chamber of powder and one chamber of liquid
Product Preparation		Product is mechanically mixed within a reusable pneumatic mixer
Biocompatibility		Biocompatible
Material Characteristics		
• **Starting Reactants**		Powder: Alpha tricalcium phosphate, Calcium carbonate (Calcite), Monocalcium phosphate monohydrate. Solution: Dilute sodium phosphate.
• **Chemical Composition**		Calcium Phosphate Salt
• **Crystal structure, after hardening**		Hydroxyapatite

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	(b) (4)	
• **Calcium to phosphate ratio**		1.67
Physical Properties		
• **Porosity**		~50%
• **Density**		~1.6-1.7 gm/cc
Performance Characteristics		
• **Injectability**		Injectable for 5 minutes
• **Working time**		~2 minutes
• **Setting Time**		~10 minutes
• **pH**		Physiologic
• **Setting reaction temperature**		Isothermic
• **Solubility and Dissolution**		Similar to hydroxyapatite
• **Bone Remodeling**		New bone grows into the graft area via osteoconduction. The material is replaced by cell mediated remodeling tissue response
Sterility		Sterilized by gamma radiation, single use only
Available Sizes		3cc, 5 cc and 10 cc kits
Voluntary Standards Met		Presumed

a. Discussion of similarities and differences

Similarities

(b) (4)

(b) (4)

Differences and Discussion

(b) (4)

Conclusion

Based on the many similarities and the minimal differences that do not negatively impact the performance of the Callos device, the clinical performance and use of both bone fillers is expected to be essentially indistinguishable. Therefore, Callos bone void filler is substantially equivalent to the predicate device, Norian SRS.

Sloan, Nadine Y.

From: duran yetkinler [duran@skeletalkinetics.com]
Sent: Wednesday, May 14, 2003 5:54 PM
To: NYR@CDRH.FDA.GOV
Subject: Changes in the Appendix H

Nadine,

It was nice speaking with you on the phone. I am forwarding the revised draft IFU to reflect the changes that we talked on the phone. I made changes to:

(b) (4)

Let me know if there are any additional questions.

Regards,

Duran

Duran N Yetkinler MD PhD
VP of Regulatory and Product Development
Skeletal Kinetics, LLC
10201 Bubb Road
Cupertino, CA 95014
Phone 408 366 5002
Fax 408 366 1077
Cell 408 757 6603

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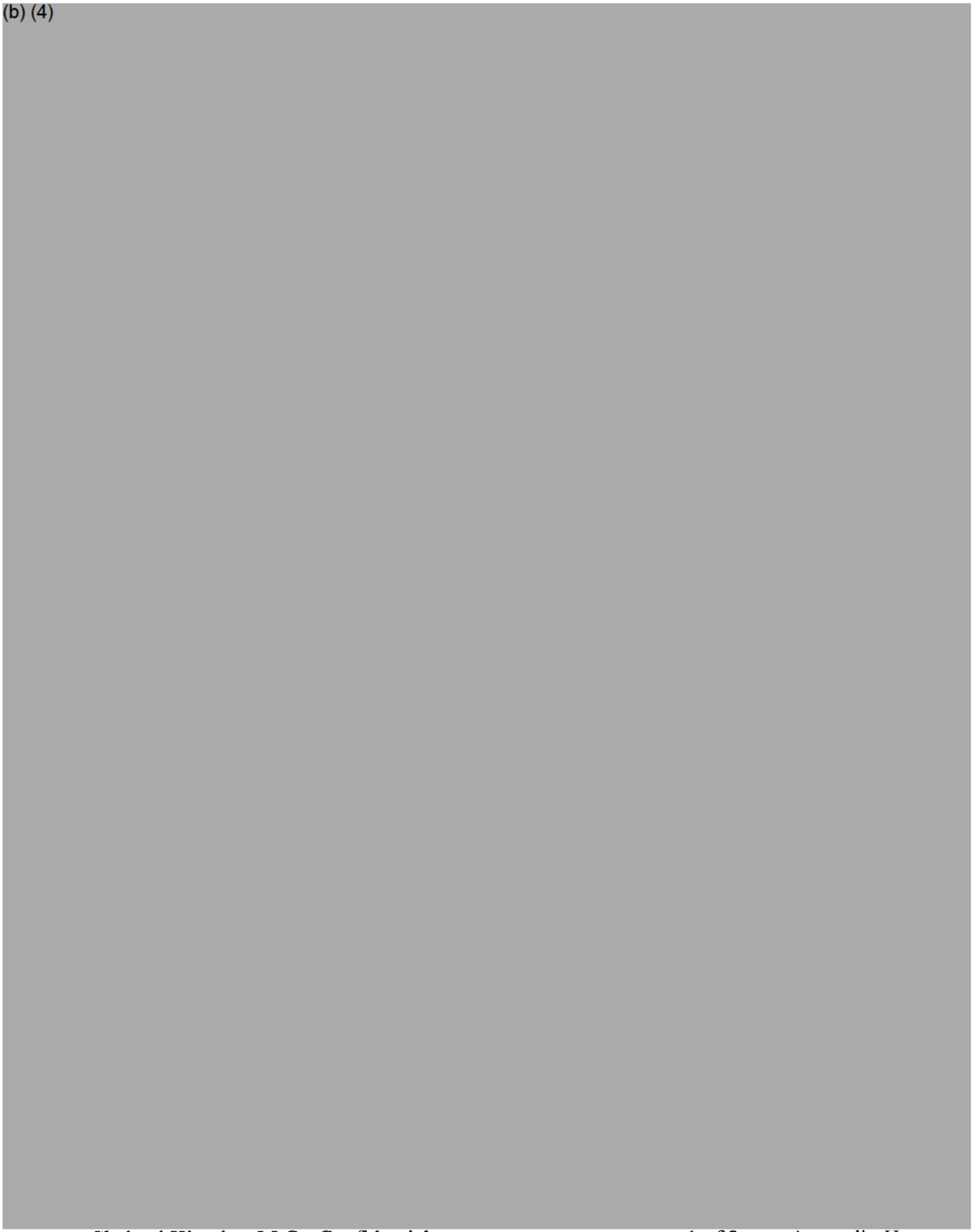
Draft IFU

(b) (4)



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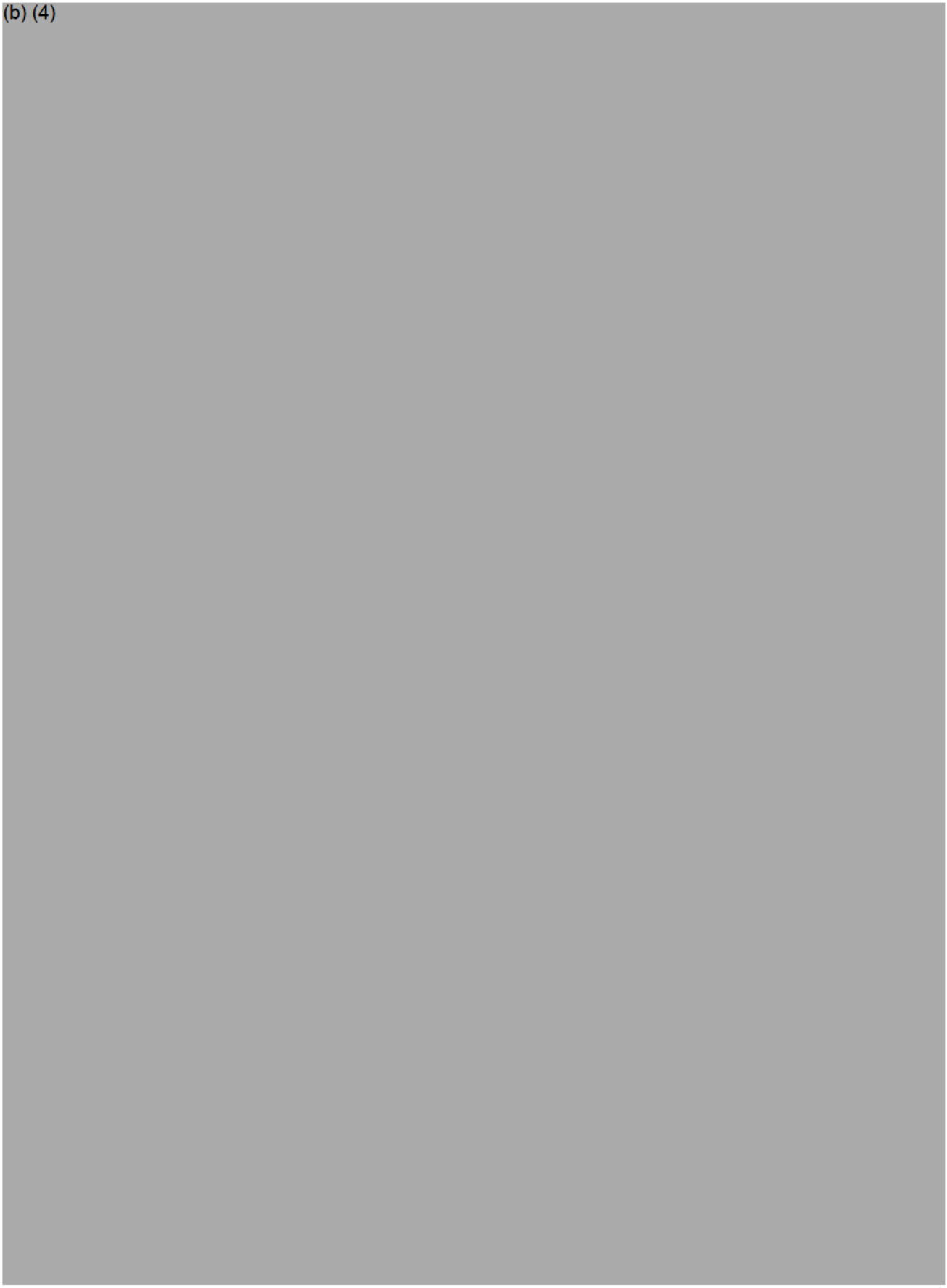

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(b) (4)

10. Instructions for Use:

(b) (4)

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K030554

The cover letter clearly identifies the type of 510(k) submission as (**Check the appropriate box**):

☐ Special 510(k) - *Do Sections 1 and 2*

☐ Abbreviated 510(k) - *Do Sections 1, 3 and 4*

☒ Traditional 510(k) or no identification provided - *Do Sections 1 and 4*

Section 1: *Required Elements for All Types of 510(k) submissions:*

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	X all present	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	See summary completed form	
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard,** which		

is posted with the 510(k) boilers on the H drive.)		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:	✓	
i) sterilization process	✓	
ii) validation method of sterilization process	✓	
iii) SAL	✓	
iv) packaging	✓	
v) specify pyrogen free	✓	
vi) ETO residues	n/a	
vii) radiation dose	✓	
viii) Traditional Method or Non-Traditional Method	✓	
c) Software Documentation:	n/a	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening: ✓ Yes ___ No

Reviewer: Valerie Swan

Concurrence by Review Branch: _____

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?	NA	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		