

APR 18 2014

**510(k) Summary**

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitted by: Biomet Trauma  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581  
Phone: (574) 372.6801  
Fax: 574.372.1683

Contact Person: Victoria Scheitlin, Regulatory Affairs Specialist

Date Prepared: March 2014

Proprietary Name: OrthoSorb LS

Common Name: Pin, Fixation, Reabsorbable, Hard Tissue

Classification Name / Product Code: Smooth or threaded metallic bone fixation fastener. (21 CFR § 888.3040) / OVZ

Predicate Devices: Biomet's OrthoSorb LS is substantially equivalent to the currently marketed devices: Depuy's Orthosorb Resorbable Pins (K901456 and K111077), and Biomet's LactoSorb Bone Pin (K990291).

Device Description: Biomet OrthoSorb LS resorbable fixation devices include straight and tapered pins. Biomet OrthoSorb LS resorbable fixation devices are made of a resorbable copolymer, polyester derivative of L-lactic and glycolic acids. Poly L-lactic/polyglycolic acid copolymer degrades and resorbs *in-vivo* by hydrolysis into L-lactic and glycolic acids which are then metabolized by the body.

Indications for Use:

- 1.) To fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals;
- 2.) For fixation of inherently stable osteotomies of the great toe and first metatarsal and intramedullary stabilization of

joint arthroplasty (resection) for the treatment of lesser toe deformities.

3.) Used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.

Technological  
Characteristics:

The technological characteristics of OrthoSorb LS are similar to currently marketed devices including design, dimensions, and material.

Summary of  
Substantial  
Equivalence:

OrthoSorb LS is substantially equivalent to currently marketed devices demonstrated through mechanical testing that was performed to ASTM D6272, which highlights the method for flexural properties, specifically testing protocol four-point bending. Single Shear testing was also performed which represents a common loading condition observed *in-vivo* during which the bone pin is used to fix bony fragments. No new issues of safety or efficacy have been raised.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Biomet Trauma  
Ms. Victoria Scheitlin  
Regulatory Specialist  
56 East Bell Drive  
Warsaw, Indiana 46581

April 18, 2014

Re: K140625

Trade/Device Name: OrthoSorb LS  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: OVZ  
Dated: March 7, 2014  
Received: March 11, 2014

Dear Ms. Scheitlin:

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

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

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

Page 2 – Ms. Victoria Scheitlin

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 contact 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

**Mark N. Melkerson -S**

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

Enclosure





One Surgeon. One Patient.  
March 7, 2014

K140625  
FDA CDRH DMC  
MAR 11 2014  
Received

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (WO66-G609)  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**SUBJECT: Traditional 510(k) Pre-Market Notification for OrthoSorb LS**

Dear Madam, Sir:

Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act (the Act) and relevant amendments thereto, Biomet is submitting the attached premarket notification for OrthoSorb LS. There are no prior submissions for the devices that are the subject of this submission. The subject devices are not in-vitro diagnostic devices.

The purpose of this submission is to notify FDA, in accordance with the 510(k) provisions of the Act, of Biomet's intent to introduce OrthoSorb LS into commercial distribution. Below are the requirements per §807.87.

<b>Device Trade / Proprietary Name</b>	OrthoSorb LS		
<b>Common / Usual Name</b>	Pin, Fixation, Resorbable, Hard Tissue		
<b>Classification Name &amp; Device Classification</b>	Class II Pin, Fixation, Resorbable, Hard Tissue	21 CFR §888.3040	OVZ
<b>Device Panel &amp; Branch</b>	Orthopedic Panel Division of General, Restorative and Neurological Devices		
<b>Owner/Operator</b>	Biomet, Inc. 56 East Bell Drive PO Box 587 Warsaw, IN 46581 Owner/Operator No. 1825034		
<b>Legal Manufacturer</b>	Biomet Trauma 56 East Bell Drive PO Box 587 Warsaw, IN 46581 Establishment Registration No. 1825034		

OrthoSorb LS Traditional 510(k)



Sterilizer	(b)(4)
Performance Standards	To the best of Biomet's knowledge, FDA has not established performance standards applicable to these devices.
Proposed Labeling	Draft labels and Instructions for Use are included in Section 13 of the submission.
Substantial Equivalence	Biomet believes that OrthoSorb LS is substantially equivalent to existing commercialized product. Refer to Section 12 of the submission for further evidence.
510(k) Summary	Refer to Section 5 of the submission.
Truthful and Accurate Statement	Refer to Section 6 of the submission.

To address the principal factors about the design and use of OrthoSorb LS, the following table is provided:

QUESTION	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	✓	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		✓
Does the device contain components derived from a tissue or other biologic source?		✓
Is the device provided sterile?	✓	
Is the device intended for single use?	✓	
Is the device a reprocessed single use device?		✓
Does the device contain a drug?		✓
Does the device contain a biologic?		✓
Does the device use software?		✓
Does the submission include clinical information?		✓
Is the device implanted?	✓	

The following additional information is also being submitted:

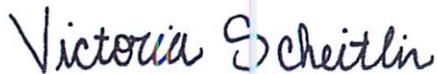
OrthoSorb LS Traditional 510(k)

- **Confidentiality:** Biomet considers its intent to manufacture this device for distribution under its own label to be confidential commercial information under 21 CFR §807.95. To the best of my knowledge, neither Biomet nor anyone else has disclosed through advertising or any other manner Biomet's intent to market the device to anyone except employees of or paid consultants to Biomet or individuals in an advertising or law firm retained by Biomet. Biomet therefore requests that FDA not disclose the existence of this notification unless and until the Agency finds the device substantially equivalent. Further, this notification contains information that is trade secret or confidential commercial information under 21 CFR §20.61 and therefore, exempt from disclosure under the Freedom of Information Act (FOIA). Biomet requests that FDA consult with the Company as provided in 21 CFR §20.47 prior to public disclosure of information contained herein.
- **Post-Market Surveillance:** It is the understanding of Biomet that FDA does not presently require the submission of postmarket surveillance plans for 510(k) devices and that manufacturers will be notified when such requirements become applicable.

Per 21 CFR §807.90(c), two copies of this Traditional Pre-Market Notification submission (one hard copy, one eCopy) plus an additional copy of the cover letter are being submitted. The eCopy is a duplicate of the hard copy.

I trust that the enclosed information is adequate to facilitate your review. Please contact me by phone 574-372-6801 or email at [victoria.scheitlin@biomet.com](mailto:victoria.scheitlin@biomet.com), should you require additional information.

Sincerely,



Victoria Scheitlin  
Regulatory Affairs Specialist  
Biomet Trauma  
Alternate contact: Suzana Otaño, Trauma RA Manager  
Ph.: (305) 269-6386 Email: [suzana.otano@biomet.com](mailto:suzana.otano@biomet.com)

Mailing Address:  
P.O. Box 637  
Warsaw, IN 46581-0637  
Tel/Fax: 800.348.9510  
Office: 574.267.6639  
Main Fax: 574.267.6107

Shipping Address:  
56 East Bell Drive  
Warsaw, IN 46582

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
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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)  BIOMET INC 56 EAST BELL DRIVE P O BOX 587 WARSAW IN 46581-0587 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME Victoria Scheitlin 2.1 E-MAIL ADDRESS victoria.scheitlin@biomet.com 2.2 TELEPHONE NUMBER (include Area code) 574-3726801 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
--	---

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm>)

Select an application type:

<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
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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       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?

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/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm> for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

- |   |   |
|---|---|
| <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates  | <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population                               |
| <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only | <input type="checkbox"/> 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       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)

06-Mar-2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES <b>FOOD AND DRUG ADMINISTRATION</b> <b>CDRH PREMARKET REVIEW SUBMISSION COVER SHEET</b>		Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See OMB Statement on page 5.		
Date of Submission 03/28/2014	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)		
<b>SECTION A TYPE OF SUBMISSION</b>				
<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
<b>SECTION B SUBMITTER, APPLICANT OR SPONSOR</b>				
Company / Institution Name Biomet Trauma		Establishment Registration Number (if known) 1825034		
Division Name (if applicable)		Phone Number (including area code) 574-372-6801		
Street Address 56 East Bell Drive		FAX Number (including area code) 574-372-1683		
City Warsaw	State / Province Indiana	ZIP/Postal Code 46581	Country United States	
Contact Name Victoria Scheitlin				
Contact Title Regulatory Specialist		Contact E-mail Address victoria.scheitlin@biomet.com		
<b>SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)</b>				
Company / Institution Name				
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City	State / Province	ZIP Code	Country	
Contact Name				
Contact Title		Contact E-mail Address		

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					
SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					

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 information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement			
1	OVZ	2	HTY	3				4	
5		6		7				8	

Information on devices to which substantial equivalence is claimed (if known)			
	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K990291	LactoSorb Bone Pins	Biomet Inc.
2	K901456	OrthoSorb	DePuy
3	K111077	OrthoSorb	DePuy
4			
5			
6			

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name  
Pin, Fixation, Reabsorbable, Hard Tissue

	Trade or Proprietary or Model Name for This Device	Model Number
1	OrthoSorb LS	See Component Lists included in the submission
2		
3		
4		
5		

FDA document numbers of all prior related submissions (regardless of outcome)					
1	None	2	3	4	5
7	8	9	10	11	12

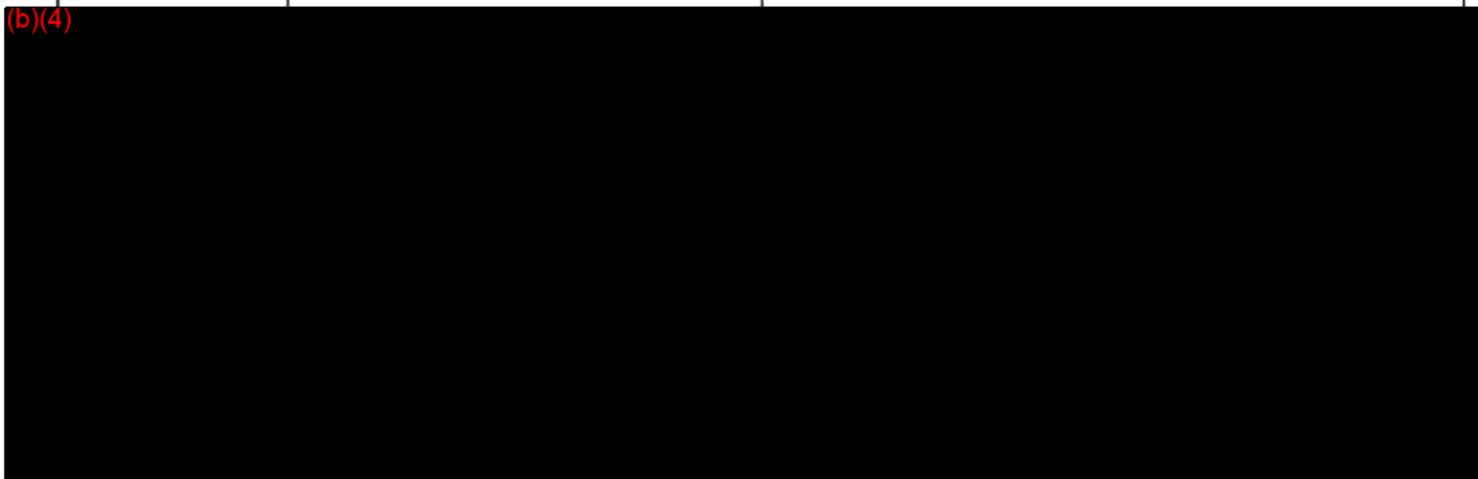
Data Included in Submission  
 Laboratory Testing       Animal Trials       Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code OVZ	C.F.R. Section (if applicable) 888.3040	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Orthopedic		

Indications (from labeling)  
See Indications For Use statement in the submission.

<b>Note:</b> Submission of the information entered in Section H does not affect the need to submit device establishment registration.		FDA Document Number (if known)	
<b>SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION</b>			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Biomet Trauma		Establishment Registration Number 1825034	
Division Name (if applicable)		Phone Number (including area code) 574-372-1553	
Street Address 56 East Bell Drive		FAX Number (including area code) 574-372-1683	
City Warsaw	State / Province Indiana	ZIP Code 46581	Country United States
Contact Name Barb Akers	Contact Title Regulatory Compliance Manager	Contact E-mail Address barb.akers@biomet.com	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler



(b)(4)

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address 301 Catrell		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

## SECTION I

## UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	F899	ASTM	Standard Specification for Wrought Stainless Steels for Surgical Instruments	12b	08/05/2013
2	D6272	ASTM	Standard Test Method for Flexural Properties of Unreinforced and Reinforced Plastics	10	04/01/2010
3	F2503	ASTM	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	13	1/30/2014
4	10993-7	AAMI/ANSI/ISO	Biological evaluation of medical devices Part 7: Ethylene Oxide sterilization residuals	CORR 1	1/15/2013
5	11135-1	ISO	Sterilization of health care products - Ethylene oxide Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.	1	3/16/2012
6	F2579	ASTM	Standard Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants	10	12/1/2010
7					

Please include any additional standards to be cited on a separate page.

**Public reporting burden for this collection of information** is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
 Food and Drug Administration  
 Office of Chief Information Officer  
 1350 Piccard Drive, Room 400  
 Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*



**Traditional 510(k)**

**Pre-Market Notification**

**for  
OrthoSorb LS**

*March 7, 2014*

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OrthoSorb LS Traditional 510(k)



One Surgeon. One Patient.  
March 7, 2014

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (WO66-G609)  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**SUBJECT: Traditional 510(k) Pre-Market Notification for OrthoSorb LS**

Dear Madam/Sir:

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The purpose of this submission is to notify FDA, in accordance with the 510(k) provisions of the Act, of Biomet's intent to introduce OrthoSorb LS into commercial distribution. Below are the requirements per §807.87.

<b>Device Trade / Proprietary Name</b>	OrthoSorb LS		
<b>Common / Usual Name</b>	Pin, Fixation, Resorbable, Hard Tissue		
<b>Classification Name &amp; Device Classification</b>	Class II	21 CFR §888.3040	OVZ
	Pin, Fixation, Resorbable, Hard Tissue		
<b>Device Panel &amp; Branch</b>	Orthopedic Panel Division of General, Restorative and Neurological Devices		
<b>Owner/Operator</b>	Biomet, Inc. 56 East Bell Drive PO Box 587 Warsaw, IN 46581 Owner/Operator No. 1825034		
<b>Legal Manufacturer</b>	Biomet Trauma 56 East Bell Drive PO Box 587 Warsaw, IN 46581 Establishment Registration No. 1825034		

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OrthoSorb LS Traditional 510(k)



One Surgeon. One Patient.

Sterilizer	(b)(4)
Performance Standards	To the best of Biomet's knowledge, FDA has not established performance standards applicable to these devices.
Proposed Labeling	Draft labels and Instructions for Use are included in Section 13 of the submission.
Substantial Equivalence	Biomet believes that OrthoSorb LS is substantially equivalent to existing commercialized product. Refer to Section 12 of the submission for further evidence.
510(k) Summary	Refer to Section 5 of the submission.
Truthful and Accurate Statement	Refer to Section 6 of the submission.

To address the principal factors about the design and use of OrthoSorb LS, the following table is provided:

QUESTION	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	✓	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		✓
Does the device contain components derived from a tissue or other biologic source?		✓
Is the device provided sterile?	✓	
Is the device intended for single use?	✓	
Is the device a reprocessed single use device?		✓
Does the device contain a drug?		✓
Does the device contain a biologic?		✓
Does the device use software?		✓
Does the submission include clinical information?		✓
Is the device implanted?	✓	

The following additional information is also being submitted:

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OrthoSorb LS Traditional 510(k)

- **Confidentiality:** Biomet considers its intent to manufacture this device for distribution under its own label to be confidential commercial information under 21 CFR §807.95. To the best of my knowledge, neither Biomet nor anyone else has disclosed through advertising or any other manner Biomet's intent to market the device to anyone except employees of or paid consultants to Biomet or individuals in an advertising or law firm retained by Biomet. Biomet therefore requests that FDA not disclose the existence of this notification unless and until the Agency finds the device substantially equivalent. Further, this notification contains information that is trade secret or confidential commercial information under 21 CFR§20.61 and therefore, exempt from disclosure under the Freedom of Information Act (FOIA). Biomet requests that FDA consult with the Company as provided in 21 CFR §20.47 prior to public disclosure of information contained herein.
- **Post-Market Surveillance:** It is the understanding of Biomet that FDA does not presently require the submission of postmarket surveillance plans for 510(k) devices and that manufacturers will be notified when such requirements become applicable.

Per 21 CFR §807.90(c), two copies of this Traditional Pre-Market Notification submission (one hard copy, one eCopy) plus an additional copy of the cover letter are being submitted. The eCopy is a duplicate of the hard copy.

I trust that the enclosed information is adequate to facilitate your review. Please contact me by phone 574-372-6801 or email at [victoria.scheitlin@biomet.com](mailto:victoria.scheitlin@biomet.com), should you require additional information.

Sincerely,



Victoria Scheitlin  
Regulatory Affairs Specialist  
Biomet Trauma  
Alternate contact: Suzana Otaño, Trauma RA Manager  
Ph.: (305) 269-6386 Email: [suzana.otano@biomet.com](mailto:suzana.otano@biomet.com)

Mailing Address:  
P.O. Box 587  
Warsaw, IN 46581-0587  
Toll Free: 800.348.6500  
Office: 574.267.6639

Shipping Address:  
56 East Bell Drive  
Warsaw, IN 46582

**RTA Screening Checklist – Traditional 510(k)**

Completed by Biomet for the convenience of the reviewer

*Contains Nonbinding Recommendations*

## Acceptance Checklist for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

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

510(k) Number: \_\_\_\_\_ Date Received by DCC: \_\_\_\_\_

Lead Reviewer Name: \_\_\_\_\_ Branch: \_\_\_\_\_ Division: \_\_\_\_\_ Office: \_\_\_\_\_

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	Yes	No
<p>1. Is the product a device (per section 201(h) of the FD&amp;C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?</p> <p>If it appears not to be a device (per section 201(h) of the FD&amp;C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."</p>	X	
<p>Comments: CDRH Coversheet (pages 3-7)</p>		
<p>2. Is the application with the appropriate Center?</p> <p>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If application should not be reviewed by your Center mark "No."</p>	X	

Comments: CDRH Coversheet (pages 3-7)		
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:		

<p>a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?</p> <p>b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?</p> <p>If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide summary of Jurisdictional Officer's/Liaison's determination.</i></p> <p>If the answer to either question above is no, mark "No." If there was no RFD, skip this question.</p>		
<p>Comments: Not applicable</p>		
<p>4. Is this device type eligible for a 510(k) submission?</p> <p>If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."</p>	X	
<p>Comments: CDRH Coversheet (pages 3-7)</p>		
<p>5. Is there a pending PMA for the same device with the same indications for use?</p> <p>If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.</p>		X
<p>Comments: No</p>		
<p>6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</p> <p>If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at <a href="http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm">http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm</a>.</p>		X

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter. If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison. If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action. If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate ER staff.

Acceptance Checklist for Traditional 510(k)

***Contains Nonbinding Recommendations***

If the answer to 6 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

<u>Organizational Elements</u>		
<i>Failure to include these items alone generally should not result in an RTA designation</i>		
	Yes	No
a. Submission contains Table of Contents	<input checked="" type="checkbox"/>	
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	<input checked="" type="checkbox"/>	
c. All pages of the submission are numbered <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	<input checked="" type="checkbox"/>	
d. Type of 510(k) is identified– traditional, abbreviated, or special <i>If type of 510(k) is not designated, review as a traditional</i>	<input checked="" type="checkbox"/>	
Comments: Traditional, identified in the CDRH Coversheet (pages 3-7)		

<u>Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)</u>				
Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
		Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
A.	Administrative			
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		Comments:		
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet ( <a href="#">Form 3514</a> ) or 510(k) cover letter):	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	a.	Device trade name or proprietary name	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b.	Device common name	<input checked="" type="checkbox"/>	<input type="checkbox"/>

***Contains Nonbinding Recommendations***

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

Submission should be designated RTA if not addressed

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

		Yes	N/A	No	
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>					
	c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Comments: Above information is contained in the CDRH Coversheet (pages 3-7)					
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) <i>Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Comments: Indications for Use Statement is included in Section 4 (page 49)					
	4.	Submission contains 510(k) Summary or 510(k) Statement <i>Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) in Comments.</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	a.	Summary contains all elements per 21 CFR 807.92 <i>See also <a href="#">510(k) Summary Checklist</a></i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b.	Statement contains all elements per 21 CFR 807.93	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments: 510(k) Summary is included in Section 5 (pages 50-51 )					
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended <a href="#">format</a>. Select "Yes" if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).</i>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Comments: Truthful and Accuracy Statement is included in Section 6 (page 52)					

Acceptance Checklist for Traditional 510(k)

***Contains Nonbinding Recommendations***

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

Submission should be designated RTA if not addressed

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

<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>		Yes	N/A	No
6.	Submission contains Class III Summary and Certification <i>See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments: Device is Class II, not applicable (page 53)				
7.	Submission contains clinical data <i>Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
a.	Submission includes completed Financial Certification ( <a href="#">FDA Form 3454</a> ) or Disclosure ( <a href="#">FDA Form 3455</a> ) information for each covered clinical study included in the submission. <i>Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the <a href="#">Guidance for Industry- Financial Disclosures by Clinical Investigators</a></i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank ( <a href="#">FDA Form 3674</a> ) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. <i>Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in <a href="#">Title VIII of FDAAA, Sec. 801(j)</a></i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments: Not applicable				
8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s ( <a href="#">FDA Form 3654</a> ) <i>There should be a completed form for each referenced national or international standard. Select "N/A" only if submission does not reference any standards.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Acceptance Checklist for Traditional 510(k)

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

Submission should be designated RTA if not addressed

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

	<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>	Yes	N/A	No
	<p>Comments: Completed Standards Data Reports - FDA Form 3654 for each referenced standard are included in Section 9 (pages 55-67)</p>			
9.	<p>The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre- Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.</p> <p><i>This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.</i></p>	<input checked="" type="checkbox"/>		<input type="checkbox"/>

***Contains Nonbinding Recommendations***

		<p>a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed.</p> <p><i>To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance “<a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm">Medical Devices: The Pre-Submission Program and Meetings with FDA Staff.</a>” (<a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm</a>). Once finalized, this guidance will represent the</i></p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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***Contains Nonbinding Recommendations***

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

Submission should be designated RTA if not addressed

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

<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>			Yes	N/A	No	
		Agency's current thinking on this topic. <i>Select "N/A" if the submitter states there were no prior submissions in criterion above.</i>				
	Comments: There have been no prior submissions for the same device as indicated in the CDRH Coversheet (pages 3-7)					
B.	Device Description					
	10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Acceptance Checklist for Traditional 510(k)

***Contains Nonbinding Recommendations***

		Comments: Not applicable, there are no device-specific guidance.
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Acceptance Checklist for Traditional 510(k)

***Contains Nonbinding Recommendations***

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

Submission should be designated RTA if not addressed

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

		Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:			
	a. A description of the principle of operation and mechanism of action for achieving the intended effect.	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	c. A list and description of each device for which clearance is requested. <i>Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Above information is included in the Device Description in Section 11 (pages 70-80)				
12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.  <i>In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed. Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Above information is included in Section 11 (pages 70-80)				

Acceptance Checklist for Traditional 510(k)

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

Submission should be designated RTA if not addressed

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

		Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, <i>Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i>		<input type="checkbox"/>	
a.	Submission includes a list of all components and accessories to be marketed with the subject device.	<input checked="" type="checkbox"/>		<input type="checkbox"/>
b.	Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. <i>Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. <i>Select "N/A" if the submission states that the component(s)/accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Above information is included in Section 11 (pages 70-80)				
C.	Substantial Equivalence Discussion			
14.	Submitter has identified a predicate(s) device	<input checked="" type="checkbox"/>		<input type="checkbox"/>

Acceptance Checklist for Traditional 510(k)

***Contains Nonbinding Recommendations***

		<p>a. Predicate's 510(k) number, trade name, and model number (if applicable) provided.                  For predicates that are preamendments devices, information is provided to document preamendments status.  <i>Information regarding <u>documenting preamendment status</u> is available online</i>  <i>(<a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidan">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidan</a></i></p>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
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Acceptance Checklist for Traditional 510(k)

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

Submission should be designated RTA if not addressed

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

		Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	<a href="http://www.fda.gov/oc/ComplianceActivities/ucm072746.htm">ce/ComplianceActivities/ucm072746.htm</a>			
	b. The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Comments: Above information is included in Section 12 (pages 81-84)				
15.	Submission includes a comparison of the following for the predicate(s) and subject device			
	a. Indications for use	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b. Technology, including features, materials, and principles of operation	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Comments: Above information is included in Section 12 (pages 81-84)				

Acceptance Checklist for Traditional 510(k)

***Contains Nonbinding Recommendations***

	<p>16. Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&amp;C Act and 21 CFR 807.87(f))</p> <p><i>If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in</i></p>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
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***Contains Nonbinding Recommendations***

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

Submission should be designated RTA if not addressed

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

		Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	<i>manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.</i>			
	Comments: Above information is included in Section 12 (pages 81-84)			
D.	Proposed Labeling (see also 21 CFR part 801) <i>If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if "N/A" is selected. IVD labeling is addressed in section 21 below.</i>		<input type="checkbox"/>	
	17. Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	a. Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	b. Submission includes directions for use that <ul style="list-style-type: none"> <li>- include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND</li> <li>- Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D</li> </ul>	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	Comments: Above information is included in Section 13 (pages 85-94)			
	18. If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also <a href="#">Alternative to Certain Prescription Device Labeling Requirements</a> ] <i>Select "N/A" if not indicated for prescription use.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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		Yes	N/A	No			
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>							
Comments: Above information is included in Section 13 (pages 85-94)							
19.	General labeling provisions						
a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)			<input checked="" type="checkbox"/>	<input type="checkbox"/>		
b.	Labeling includes device common or usual name (21 CFR 801.61) <i>Select "N/A" if device is for prescription use only.</i>			<input type="checkbox"/>	<input checked="" type="checkbox"/>		
Comments: Above information is included in Section 13 (pages 85-94)							
20.	a.	If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i>			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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		Yes	N/A	No
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	<p>c. If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i></p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<p>Comments: Not applicable, no device-specific guidance associated with the subject devices.</p>				
	<p>21. If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. <i>Select "N/A" if not an in vitro diagnostic device.</i></p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
E.	<p><b>Sterilization</b> <i>If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.</i></p>		<input type="checkbox"/>	
	<p>Submission states that the device and/or accessories are: <i>(one of the below must be checked)</i></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> provided sterile</li> <li><input type="checkbox"/> provided non-sterile but sterilized by the end</li> <li><input type="checkbox"/> user non-sterile when used</li> </ul> <p>This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "non-sterile when used" is selected, the sterility-related criteria below are omitted from</i></p>			<input type="checkbox"/>

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	Yes	N/A	No
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*the checklist.*  
*If information regarding the sterility status of the device is not provided, select "No."*

Comments: Above information included in Section 14 (pages 95-96)

22. Assessment of the need for sterilization information

			Yes	N/A	No
	a.	Identification of device, and/or accessories, and/or components that are provided sterile.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b.	Identification of device, and/or accessories, and/or components that are end user sterilized	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Comments: Above information included in Section 14 (pages 95-96)

23. If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.*

			Yes	N/A	No
	a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. <i>Note, the sterilization validation report is not required.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

		Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	levels of sterilant residuals remaining on the device and sterilant residual limits. <i>Select “N/A” if not sterilized using chemical sterilants.</i>			
d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	<input checked="" type="checkbox"/>		<input type="checkbox"/>
e.	Sterility Assurance Level (SAL) stated	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Comments: Above information included in Section 14 (pages 95-96)				
24.	If the device, and/or accessory, and/or a component is end user sterilized: <i>Select “N/A” if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.</i>		<input checked="" type="checkbox"/>	
a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. <i>Note, the sterilization validation is not required.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
d.	Submission includes sterilization instructions for end user	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments: Not Applicable.				
25.	a. If there are requirements regarding sterility, such as special	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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

			Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>					
		controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>			
	b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a</i>		<input checked="" type="checkbox"/>	

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<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>		Yes	N/A	No
	<i>special controls document have been addressed should be assessed during the substantive review.</i>			
	Comments: There is no special controls document applicable to the subject devices.			
F.	Shelf Life			
	26. Proposed shelf life/ expiration date stated <i>Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Comments: Above information included in Section 14 (pages 95-96)			
	27. For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. <i>Select "N/A" if the device is not provided sterile.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Comments: Above information included in Section 14 (pages 95-96)			
	28. Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	<input checked="" type="checkbox"/>		<input type="checkbox"/>
	Comments: Above information included in Section 14 (pages 95-96)			
G.	Biocompatibility <i>If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.</i>		<input type="checkbox"/>	
	Submission states that there: <i>(one of the below must be checked)</i> <input checked="" type="checkbox"/> are			<input type="checkbox"/>

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

		Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	<input type="checkbox"/> are not direct or indirect (e.g., through fluid infusion) patient-contacting components.  This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."</i>			
Comments: Above information included in Section 15 (pages 97-101)				
29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Comments: Above information included in Section 15 (pages 97-101)				
30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Comments: Above information included in Section 15 (pages 97-101)				
31.	Biocompatibility assessment of patient-contacting components  Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	<input checked="" type="checkbox"/>		<input type="checkbox"/>
Comments: Above information included in Section 15 (pages 97-101)				
H.	Software			

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		Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	<p>Submission states that the device: <i>(one of the below must be checked)</i></p> <p><input type="checkbox"/> does</p> <p><input checked="" type="checkbox"/> does not contain software/firmware.</p> <p>This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.  <i>If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."</i></p>			
	Comments: Statement that the submission does not included software is included in Section 16 (page 102)			
32.	Submission includes a statement of software level of concern and rationale for the software level of concern	<input type="checkbox"/>		<input type="checkbox"/>
	Comments: Not applicable			
33.	All applicable software documentation provided based on level of concern identified by the submitter, as described in <a href="#">Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</a> , or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	<input type="checkbox"/>		<input type="checkbox"/>
	Comments: Not applicable			
I.	EMC and Electrical Safety			
	<p>Submission states that the device: <i>(one of the below must be checked)</i></p> <p><input type="checkbox"/> does</p> <p><input checked="" type="checkbox"/> does not require EMC and Electrical Safety evaluation.</p>			<input type="checkbox"/>

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		Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
<p>This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.  <i>If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."</i></p>				
<p>Comments: Statement that the submission contains MRI information is included in Section 17 (page103-106)</p>				
34.	<p>Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard),                      OR                      submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).</p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<p>Comments: Not applicable</p>				
35.	<p>Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard)                      OR                      submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).</p>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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		Comments: MRI statement information included (pages 103-106)
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J.	Performance Data – General <i>If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.</i>		<input checked="" type="checkbox"/>	
Comments: Not applicable				
36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.  <i>Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments: Above information is provided in Section 18 (pages 107-119)				
37.	a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. <i>Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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	<p>approach.  <i>Select "N/A" if there is no applicable device-specific guidance.                      Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i></p>			
	<p>c. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.  <i>Select "N/A" if there is no applicable special controls document.                      Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i></p>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<p>Comments: There are no device-specific guidances for the subject devices.</p>				
	<p>38. If literature is referenced in the submission, submission includes:  <i>Select "N/A" if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.</i></p>		<input checked="" type="checkbox"/>	
	<p>a. Legible reprints or a summary of each article</p>	<input type="checkbox"/>		<input type="checkbox"/>

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		b.	Discussion of how each article is applicable to support the	<input type="checkbox"/>		<input type="checkbox"/>
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		Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
	substantial equivalence of the subject device to the predicate.			
	Comments: Not applicable, literature not required to demonstrate substantial equivalence of the subject devices to the predicates.			
39.	For each completed nonclinical (i.e., animal) study conducted, Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,		<input checked="" type="checkbox"/>	
	a. Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	<input type="checkbox"/>		<input type="checkbox"/>
	b. Submission includes final study report which includes all elements outlined in 21 CFR 58.185	<input type="checkbox"/>		<input type="checkbox"/>
	c. Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	<input type="checkbox"/>		<input type="checkbox"/>
	Comments: Not applicable, animal testing not required for demonstrating substantial equivalence of the subject devices to the predicates.			
K.	Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))		<input checked="" type="checkbox"/>	
	Submission indicates that device: ( <i>one of the below must be checked</i> )  <input type="checkbox"/> is <input checked="" type="checkbox"/> is not an in vitro diagnostic device (IVD). <i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i>			
	Comments: Statement that the device is not an IVD is included in the CDRH Coversheet (pages 3-7)			

Acceptance Checklist for Traditional 510(k)

***Contains Nonbinding Recommendations***

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

Submission should be designated RTA if not addressed

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

		Yes	N/A	No
<ul style="list-style-type: none"> <li>- Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>				
40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:			
	a. Precision/reproducibility	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b. Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff).	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	c. Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	d. Analytical specificity	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments: Not Applicable				
41.	a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. <i>Select “N/A” if there are no applicable requirements in a device- specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Acceptance Checklist for Traditional 510(k)

***Contains Nonbinding Recommendations***

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

Submission should be designated RTA if not addressed

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

<ul style="list-style-type: none"> <li>- Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.</li> </ul>			Yes	N/A	No
		applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i>			
		C. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments: Not Applicable					

Acceptance Checklist for Traditional 510(k)

***Contains Nonbinding Recommendations***

Decision: Accept \_\_\_\_\_ Refuse to Accept \_\_\_\_\_

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Reviewer Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Supervisor Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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**Section 4 – Indications for Use Statement**

**510(k) Number:** \_\_\_\_\_

**Device Name:** OrthoSorb LS

**Indications For Use:**

- 1.) To fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals;
- 2.) For fixation of inherently stable osteotomies of the great toe and first metatarsal and intramedullary stabilization of joint arthroplasty (resection) for the treatment of lesser toe deformities.
- 3.) Used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.

Prescription Use   **X**    
(Per 21 CFR 801 Subpart D)

AND/OR Over-the-Counter \_\_\_\_\_  
(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)

## Section 5 – 510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitted by: Biomet Trauma  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581  
Phone: (574) 372.6801  
Fax: 574.372.1683

Contact Person: Victoria Scheitlin, Regulatory Affairs Specialist

Date Prepared: March 2014

Proprietary Name: OrthoSorb LS

Common Name: Pin, Fixation, Reabsorbable, Hard Tissue

Classification Name / Product Code: Smooth or threaded metallic bone fixation fastener. (21 CFR § 888.3040) / OVZ

Predicate Devices: Biomet's OrthoSorb LS is substantially equivalent to the currently marketed devices: Depuy's Orthosorb Resorbable Pins (K901456 and K111077), and Biomet's LactoSorb Bone Pin (K990291).

Device Description: Biomet OrthoSorb LS resorbable fixation devices include straight and tapered pins. Biomet OrthoSorb LS resorbable fixation devices are made of a resorbable copolymer, polyester derivative of L-lactic and glycolic acids. Poly L-lactic/polyglycolic acid copolymer degrades and resorbs *in-vivo* by hydrolysis into L-lactic and glycolic acids which are then metabolized by the body.

Indications for Use:

- 1.) To fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals;
- 2.) For fixation of inherently stable osteotomies of the great toe and first metatarsal and intramedullary stabilization of

joint arthroplasty (resection) for the treatment of lesser toe deformities.

3.) Used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.

Technological  
Characteristics:

The technological characteristics of OrthoSorb LS are similar to currently marketed devices including design, dimensions, and material.

Summary of  
Substantial  
Equivalence:

OrthoSorb LS is substantially equivalent to currently marketed devices demonstrated through mechanical testing that was performed to ASTM D6272, which highlights the method for flexural properties, specifically testing protocol four-point bending. Single Shear testing was also performed which represents a common loading condition observed *in-vivo* during which the bone pin is used to fix bony fragments. No new issues of safety or efficacy have been raised.

**Section 6 – Truthful and Accuracy Statement**

**PREMARKET NOTIFICATION  
TRUTHFUL AND ACCURATE STATEMENT**

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as a Development Engineer for Biomet, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)



Research Scientist, Biomaterials Research

3/3/2014

Date

I certify that, in my capacity as a Regulatory Affairs Specialist, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Victoria Scheitlin

Victoria Scheitlin  
Regulatory Affairs Specialist

3/4/2014

Date

\_\_\_\_\_  
(Premarket Notification [510(k)] Number)

OrthoSorb LS Traditional 510(k)  
**CONFIDENTIAL**

**Section 7 – Class III Summary and Certification**

This section is not applicable because OrthoSorb LS is not a Class III device.

**Section 8 – Financial Certification or Disclosure Statement**

This section is not applicable because clinical studies were not conducted for the OrthoSorb LS submission.

## Section 9 – Declaration of Conformity

EN ISO 11135-1	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
AAMI/ANSI/ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
ASTM F899-12	Standard Specification for Wrought Stainless Steels for Surgical Instruments
ASTM D6272-10	Standard Test Method for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials by Four-Point Bending
ASTM F2503-13	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ASTM F2579 - 10	Standard Specification for Amorphous Poly (lactide) and Poly (lactide-co-glycolide) Resins for Surgical Implants

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11135-1 Sterilization of health care products - Ethylene oxide - Part 1

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #14-331

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

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 <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 11135-1 Sterilization of health care products - Ethylene oxide - Part 1

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

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.

<sup>♦</sup> 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Office of Chief Information Officer  
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PRASStaff@fda.hhs.gov

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

AAMI ANSI ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #14-278

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

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 <sup>6</sup> that is associated with this standard?.....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
AAMI ANSI ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM 2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #8-349

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ASTM 2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM D6272 Standard Test Method for Flexural Properties of Unreinforced and Reinforced Plastics

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes     No

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes     No

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....  Yes     No  
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? .....  Yes     No

Does this standard include acceptance criteria? .....  Yes     No  
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....  Yes     No  
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....  Yes     No  
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....  Yes     No

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....  Yes     No  
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....  Yes     No  
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....  Yes     No  
If yes, was the guidance document followed in preparation of this 510k? .....  Yes     No

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> 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>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ASTM D6272 Standard Test Method for Flexural Properties of Unreinforced and Reinforced Plastics

**CONFORMANCE WITH STANDARD SECTIONS\***

<b>SECTION NUMBER</b> 4.1	<b>SECTION TITLE</b> Summary of Test Method	<b>CONFORMANCE?</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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**TYPE OF DEVIATION OR OPTION SELECTED** ♦  
This standard is not recognized by FDA, therefore no SIS guidance is available for this standard. Specimen geometry was a circular cross sectional area, rather than a rectangular cross sectional area, as called out in this standard.

**DESCRIPTION**  
Bone pin geometry's are 1.3mm or 2.0mm in diameter.

**JUSTIFICATION**  
The same testing parameters and conditions were utilized in testing the specimens, OrthoSorb LS, and OrthoSorb.

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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**TYPE OF DEVIATION OR OPTION SELECTED** ♦

**DESCRIPTION**

**JUSTIFICATION**

<b>SECTION NUMBER</b>	<b>SECTION TITLE</b>	<b>CONFORMANCE?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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**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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
(To be filled in by applicant)

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 <sup>1</sup>

ASTM F2579-10 Standard Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes     No

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes     No

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....  Yes     No  
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? .....  Yes     No

Does this standard include acceptance criteria? .....  Yes     No  
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....  Yes     No  
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....  Yes     No  
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....  Yes     No

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....  Yes     No  
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....  Yes     No  
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard?.....  Yes     No  
If yes, was the guidance document followed in preparation of this 510k? .....  Yes     No

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ASTM F2579-10 Standard Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services  
 Food and Drug Administration  
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 (To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F899-12b, Standard Specification for Stainless Steel for Surgical Instruments (Materials)

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #8-343

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....       
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

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 <sup>6</sup> that is associated with this standard?.....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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<sup>5</sup> 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>

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ASTM F899-12b, Standard Specification for Stainless Steel for Surgical Instruments (Materials)

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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## Section 10 – Executive Summary

Biomet's OrthoSorb LS is an internal fixation device intended to aid the surgeon in the alignment and stabilization of skeletal fractures and to provide a means of fracture management in reconstructive surgical applications. Biomet OrthoSorb LS resorbable fixation devices are available in two forms to the surgeon, straight and tapered resorbable pins and in two diameters.



Biomet's OrthoSorb LS tapered and straight pins are made of a resorbable copolymer, which is a polyester derivative of L-lactic and glycolic acids. Once implanted Poly L-lactic / Polyglycolic acid (PLLA/PGA) copolymer degrades and resorbs *in-vivo* by hydrolysis into L-lactic and glycolic acids which are then metabolized by the body, refer to **Section 18** for specific mechanical data. The OrthoSorb LS material is the same as Biomet's LactoSorb resorbable material which is machined from extruded LactoSorb L1 (82% PLLA-18% PGA copolymer) barstock, cleared via K990291. Biomet resorbable fixation devices are made of a resorbable copolymer, polyester derivative of L-lactic and glycolic acids. Poly L-lactic (PLLA) / Polyglycolic acid (PGA) copolymer degrades and resorbs *in-vivo* by hydrolysis into L-lactic and glycolic acids which are then metabolized by the body. The extruded LactoSorb barstock is produced directly from a PLGA resin. This material has been clinically available and used for bioabsorbable internal fixation devices for the past twenty years, **Section 15** of this submission discusses the Biocompatibility of OrthoSorb LS.

The OrthoSorb LS tapered pin is available in a 1.3mm diameter pin with applicator kit, which contains dimensionally optimized instruments. The OrthoSorb LS tapered pin is intended to be used for through-and-through applications in the hand and foot. The tapered pins are used to fix in place small bony or chondral fragments in the hand where such fragments are not in tension, as in the case of fractures of the phalanges and metacarpals. The tapered OrthoSorb LS is used for the fixation of inherently stable osteotomies of the great toe and first metatarsal. The tapered pin also, is used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are employed. Respective part numbers and drawings for the OrthoSorb LS tapered pin are located in **Section 11**.



**Figure 1: OrthoSorb LS in stage 2 of resorption, 9-15 months.**

The OrthoSorb LS straight pins are available in 1.3mm and 2.0mm diameter with applicator kit, which contains dimensionally optimized instruments for each pin's specific diameter. The straight pins are intended to be used to fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals, fixation of inherently stable osteotomies of the great toe and first metatarsal and intramedullary stabilization of joint arthroplasty (resection) for the treatment of lesser toe deformities, and used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed. Respective part numbers and drawings for the OrthoSorb LS straight pins are located in **Section 11**.

The Biomet OrthoSorb LS resorbable tapered pin and the 1.3mm and 2.0mm resorbable straight pins with applicator kit will be supplied to the surgeon in sterile configurations. The kits are sterilized by (b)(4)

Further information regarding the OrthoSorb LS resorbable tapered and straight pins sterility and shelf life located in the Sterilization and Shelf Life, **Section 14**. OrthoSorb LS will be offered in two configurations. The 1.3 mm and 2.0mm OrthoSorb LS straight pins will be offered in kits of one or three resorbable pins. The 1.3mm OrthoSorb LS tapered pin is offered in a single pin kit.

The packaging configuration for both OrthoSorb LS 1.3mm resorbable tapered pin with applicator kit and the OrthoSorb LS 1.3mm and 2.0mm resorbable pin with applicator kit are identical. A thermoformed tray sealer is used which individually heat seals a Tyvek lid to a PETG tray, this functions as the sterile barrier. The sealed PETG tray with the Tyvek lid is then packaged into an outer foil pouch with a desiccant pouch that functions as the moisture barrier. The PETG tray and foil pouch are then placed into an outer protective carton.

## Section 11 - Device Description

Biomet's OrthoSorb LS is an internal fixation device intended to aid the surgeon in the alignment and stabilization of skeletal fractures and to provide a means of fracture management in reconstructive surgical applications. Biomet OrthoSorb LS resorbable fixation devices are available in two forms to the surgeon, straight and tapered resorbable pins and in two diameters.

The OrthoSorb LS tapered pin is available in a 1.3mm diameter pin with applicator kit, which contains dimensionally optimized instruments. The OrthoSorb LS tapered pin is intended to be used for through-and-through applications in the hand and foot. The tapered pins are used to fix in place small bony or chondral fragments in the hand where such fragments are not in tension, as in the case of fractures of the phalanges and metacarpals. The tapered OrthoSorb LS is used for the fixation of inherently stable osteotomies of the great toe and first metatarsal. The tapered pin also, is used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are employed. Respective part numbers and drawings for the OrthoSorb LS tapered pin are located later in this section.



The OrthoSorb LS straight pins are available in 1.3mm and 2.0mm diameters with applicator kit, which contains dimensionally optimized instruments. The straight pins are intended to be used to fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of



osteochondritis dissecans or fractures of the phalanges and metacarpals, fixation of inherently stable osteotomies of the great toe and first metatarsal and intramedullary stabilization of joint arthroplasty (resection) for the treatment of lesser toe deformities, and used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.

Respective part numbers and drawings for the OrthoSorb LS straight pins are located later in this section.

OrthoSorb LS 1.3mm and the 2.0mm straight pins as well as the OrthoSorb LS tapered pin are available at a length of 40 mm for the straight pins and 101mm for the tapered pin. The diameter and type of pin utilized is up to the surgeon's discretion and intended use. Upon insertion the pins can be cut to the appropriate length using a heat loop. The instructions for use can be found in the Draft Labeling and Surgical Techniques located in **Section 13**.

Biomet's OrthoSorb LS tapered and straight pins are made of a resorbable copolymer, which is a polyester derivative of L-lactic and glycolic acids. Once implanted Poly L-lactic / polyglycolic acid (PLLA/PGA) copolymer degrades and resorbs *in-vivo* by hydrolysis into L-lactic and glycolic acids which are then metabolized by the body, refer to **Section 18** for specific mechanical data. The OrthoSorb LS material is the same as Biomet's LactoSorb resorbable material, which is machined from extruded LactoSorb L1 (82% PLLA-18% PGA copolymer) barstock, cleared via K990291. Biomet resorbable fixation devices are made of Poly L-lactic (PLLA) / Polyglycolic acid (PGA) copolymer, which creates a Poly Lactic-co-Glycolic Acid (PLGA) which is a resorbable copolymer, polyester derivative of L-lactic and glycolic acids. The OrthoSorb LS PLGA material degrades and resorbs *in- vivo* by hydrolysis into L-lactic and glycolic acids which are then metabolized by the body. The extruded LactoSorb barstock is produced directly from a PLGA resin. Visually OrthoSorb LS is a clear or amber in color, which is the natural color of PLGA, color additives are not added to OrthoSorb LS. This material has been clinically available and used for bioabsorbable internal fixation devices for the past twenty years, **Section 15** of this submission discusses the Biocompatibility of OrthoSorb LS. Biomet Once implanted Poly L-lactic/polyglycolic acid copolymer degrades and resorbs *in- vivo* by hydrolysis into L-lactic and glycolic acids which are then metabolized by the body, refer to **Section 18** for specific mechanical data.



Figure 1: OrthoSorb LS in stage 2 of resorption, 9-15 months.

Biomet's OrthoSorb LS tapered and straight pins applicator kits contain instruments that are dimensionally optimized to the size of implant. The OrthoSorb LS straight and tapered implants are class II, marketed under the product code OVZ, per 21 CFR §888.3040. The offering list of the OrthoSorb LS straight and tapered kits are identified in **Table 1**. The instruments available in the applicator kit are K-wires, Pin Gauge, Tubes and a Pusher. The instruments are only offered in sterile options within the implant kits and are intended to be disposed of after initial use. The instruments that are housed within the applicator kit are designed for specific use with this system and therefore considered specialized instruments. For completeness in this submission, the instruments are identified in **Table 2**. Implant specific instruments are class II, taking on the same classification as the subject implant, OVZ, per 21 CFR §888.3040. The respective drawings for the OrthoSorb LS kits are located in this section.

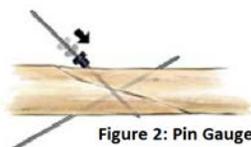


Figure 2: Pin Gauge

The OrthoSorb LS resorbable implant kits are discussed in **Table 1** and **Table 2** discussed the implants that are included in the finished kit product offerings to the surgeon. Respective drawings are located in this section.

**Table 1: Implants and Applicator Kit Product offerings, Materials, Standards**

Product Number	Description	Implant Material:	Implant Material Standard:
110010741	OrthoSorb LS 1.3 mm Straight Pin Kit 1 Pin, 1 Pack	82% PLLA-18% PGA copolymer (PLGA)	ASTM F2579
110010742	OrthoSorb LS 1.3 mm Straight Pin Kit 3 Pins, 1 Pack	82% PLLA-18% PGA copolymer (PLGA)	ASTM F2579
110010743	OrthoSorb LS 2.0 mm Straight Pin Kit 1 Pin, 1 Pack	82% PLLA-18% PGA copolymer (PLGA)	ASTM F2579
110010744	OrthoSorb LS 2.0 mm Straight Pin Kit 3 Pins, 1 Pack	82% PLLA-18% PGA copolymer (PLGA)	ASTM F2579
110010745	OrthoSorb LS 1.3 mm Tapered Pin Kit	82% PLLA-18% PGA copolymer (PLGA)	ASTM F2579

**Table 2: Specialized Instrumentation (Bone contact, External communicating, Direct Contact, Limited Contact, ≤24 hours)**

Product Number:	Description:	Material:	Standard:
110017450	1.3mm K-wire	(b)(4)	ASTM F899
110017416 110017413	1.3mm Pin Gauge		ASTM F899 (for 302 SS)
110017442	1.3mm Pusher		ASTM F899
110017446	1.3mm Tube		ASTM F899
110017451	2.0mm K-wire		ASTM F899
110017458	2.0mm Pusher		ASTM F899
110017452	2.0mm Tube		ASTM F899

The Biomet OrthoSorb LS resorbable tapered pin and the 1.3mm and 2.0mm resorbable straight pins with applicator kit will be supplied to the surgeon in sterile configurations. The kits are sterilized by (b)(4)

(b)(4) Further information regarding the OrthoSorb LS resorbable tapered and straight pins sterility and shelf life located in the Sterilization and Shelf Life, **Section 14**. OrthoSorb LS will be offered in two configurations. The 1.3 mm and

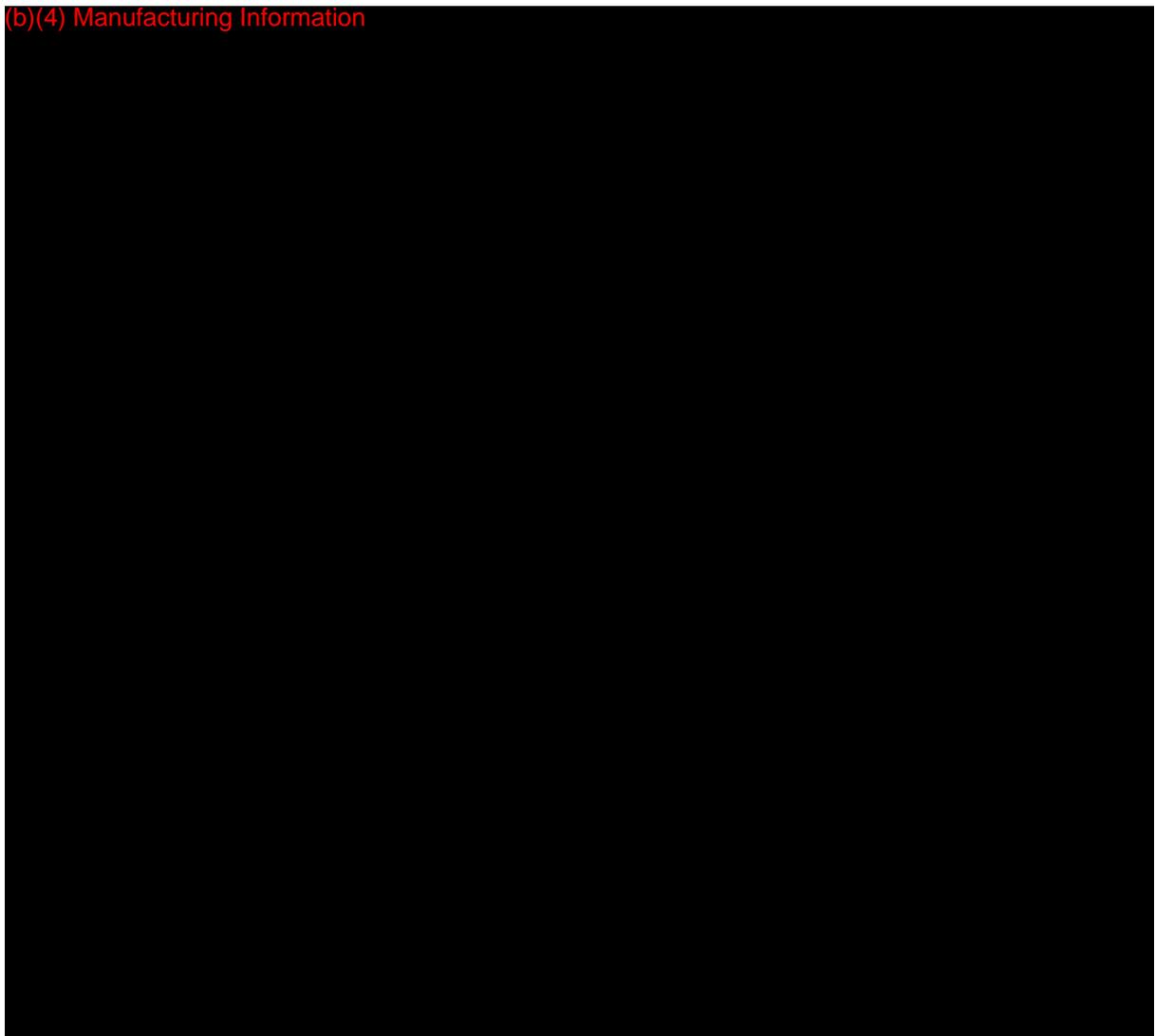
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OrthoSorb LS Traditional 510(k)

2.0mm OrthoSorb LS straight pins will be offered in kits of one or three resorbable pins. The 1.3mm OrthoSorb LS tapered pin is offered in a single pin kit.

The packaging configuration for both OrthoSorb LS 1.3mm resorbable tapered pin with applicator kit and the OrthoSorb LS 1.3mm and 2.0mm resorbable pin with applicator kit are identical. A thermoformed tray sealer is used which individually heat seals a Tyvek lid to a PETG tray, this functions as the sterile barrier. The sealed PETG tray with the Tyvek lid is then packaged into an outer foil pouch with a desiccant pouch that functions as the moisture barrier. The PETG tray and foil pouch are then placed into an outer protective carton.

(b)(4) Manufacturing Information



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OrthoSorb LS Traditional 510(k)















## Section 12 – Substantial Equivalence Discussion

Biomet's OrthoSorb LS is an internal fixation device intended to aid the surgeon in the alignment and stabilization of skeletal fractures and provide a means of fracture management in reconstructive surgical applications. Biomet OrthoSorb LS resorbable fixation devices are available in two forms to the surgeon, straight and tapered pins.

The design of OrthoSorb LS includes straight and tapered pin designs. The dimensions of OrthoSorb LS straight pins are available in diameters of 1.3mm and 2.0mm and in a length of 40mm for the straight pin, and 101mm for the tapered pin. The Biomet LactoSorb Bone Pins (K990291) predicate devices are available in straight pin configurations with diameters of 1.5mm, 2.0mm, 2.4mm, and 3.2mm with lengths ranging from 20mm-70mm. The DePuy predicate OrthoSorb (K111077 and K901456) has a straight pin design with diameters of 1.3mm and 2.0mm, with a length of 40mm for the straight pin, and 250mm for the tapered. The Biomet OrthoSorb LS tapered pin is offered in a diameter of 1.3mm, with a length of 101mm. Biomet's OrthoSorb LS tapered pin is a free standing implant with no instruments attached. The Biomet LactoSorb Bone Pins (K990291) devices are not offered in a tapered pin design. DePuy's OrthoSorb (K111077 and K901456) is offered in a tapered pin design with a 1.3mm diameter and a length of 250mm, with an attached k-wire.



The Biomet indications for the resorbable bone pins include fixation of inherently stable osteotomies of the great toe, as well as the first metatarsal. This indication is based upon published literature on how it is common to use resorbable pins in the correction of osteotomies in first metatarsal. A publication was released in 1994, by Dr. Raymond Caualiere, discussing the use of OrthoSorb in correcting first metatarsal osteotomies. This publication concluded that the use of OrthoSorb to correct first metatarsal osteotomies was successful, and that no postoperative disruption of the osteotomy has occurred to date<sup>2</sup>. The next publication written by L.A. Laverly discuss the comparison of using Polyglycolic Acid pins and Steinmann pins in closing base wedge osteotomies of the first metatarsal bone.<sup>3</sup> This article stated that the structural characteristics of the

absorbable pins were the same as stainless steel pins at the time of initial placement. Therefore, based on the long clinical use of resorbable bone pins utilized for corrections of osteotomies in first metatarsal, including the predicate device, Biomet has chosen to include first metatarsal osteotomies in the indications for use statement.

The material used to fabricate Biomet's OrthoSorb LS tapered and straight pins are a resorbable copolymer, which is a polyester derivative of L-lactic and glycolic acids, which is machined from extruded LactoSorb L1 (82%PLLA-18%PGA) barstock. The extruded LactoSorb barstock is produced directly from PLGA resin. The OrthoSorb LS tapered and straight pins are manufactured by extrusion manufacturing methods. The OrthoSorb LS material is the same material as the Biomet LactoSorb Bone Pins (K990291). DePuy's OrthoSorb is fabricated from Poly-p-Dioxanone. The Poly-p-Dioxanone is synthesized through a process of ring-opening polymerization of para-dioxanone, with flexibility in a monofilament form.

The mechanical retention strength of new OrthoSorb LS (b)(4) material is capable of retaining 70% of its mechanical strength at 6-8 weeks *in vitro*. This strength retention is due to the material being more rigid. The Biomet LactoSorb Bone Pins (K990291), retain the same strength as OrthoSorb *in vitro*. DePuy's OrthoSorb retains 50% of its mechanical strength at 7.2 weeks<sup>1</sup>.

As a summary, a comparison matrix between Biomet's OrthoSorb LS and the predicate devices is provided in **Table 3**.

1. DePuy ACE Medical Company. "Advances in Absorbable Technology Lead to the Development of OrthoSorb Products." (n.d.): n. pag. DePuy.com. Web.  
<[http://www.depuy.com/sites/default/files/products/files/DO\\_Orthosorb\\_Pins\\_Product\\_Brochure\\_TOS-314r1.pdf](http://www.depuy.com/sites/default/files/products/files/DO_Orthosorb_Pins_Product_Brochure_TOS-314r1.pdf)>.

2. Caualiere, Raymond G., D.P.M. "Distal First Metatarsal Osteotomies and Orthosorb Fixation." N.p.: n.p., n.d. N. pag. *Podiatry Institute*. Web.  
<[http://www.podiatryinstitute.com/pdfs/Update\\_1994/1994\\_20.pdf](http://www.podiatryinstitute.com/pdfs/Update_1994/1994_20.pdf)>.

3. L.A., Lavery. "Stability of Absorbable Fixation in Basilar First Metatarsal Osteotomies." *Journal of the American Podiatric Medical Association* (1993): n. pag. *NCBI*. Web.  
<<http://www.ncbi.nlm.nih.gov/pubmed/8229703>>.

Table 3: Device Comparison

<u>Characteristics:</u>	Subject of this submission	DePuy OrthoSorb K111077 &K901456	LactoSorb Bone Pins K990291
<u>Product Code:</u>	OVZ	OVZ	HTY
<u>Materials:</u>	82% PLLA / 18% PGA	Poly-p-Dioxanone	82% PLLA / 18% PGA
<u>Indications for Use:</u>	<p>1.) To fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals;</p> <p>2.) For fixation of inherently stable osteotomies of the great toe and first metatarsal and intramedullary stabilization of joint arthroplasty (resection) for the treatment of lesser toe deformities.</p> <p>3.) Used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.</p>	<p>The OrthoSorb Resorbable pin are indicated for use to fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals; or for fixation of inherently stable osteotomies of the great toe and intramedullary stability of joint arthroplasty (resection) for the treatment of lesser toe deformities. The Resorbable Pin can be used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.</p>	<p>LactoSorb Bone Pins are for use in the presence of appropriate immobilization in the following procedures:</p> <ol style="list-style-type: none"> <li>1. Correction of hallux valgus</li> <li>2. Repair of metacarpal and phalangeal fusion and fractures</li> </ol>
<u>Design:</u>	<p><u>Straight Pins:</u> 1.3mm and 2.0mm diameter</p> <p><u>Tapered Pin :</u> 1.3mm</p>	<p><u>Straight Pins :</u> 1.3mm, 2.0mm</p> <p><u>Tapered Pin (Connected to a k-wire):</u> 1.3mm</p>	<p><u>Straight Pins :</u> 1.5mm, 2.0mm, 2.4mm, 3.2mm</p>
<u>Length:</u>			
<u>Straight Pin:</u>	40mm	40mm	20-70mm
<u>Tapered Pin:</u>	101mm	250mm	N/A
<u>Characteristics:</u>	Subject of this submission	DePuy OrthoSorb K111077 &K901456	LactoSorb Bone Pins K990291
<u>Malleability:</u>	Rigid	Highly Flexible	Rigid
<u>50% Mechanical Strength Retention:</u>	70% Retention at 6-8 weeks in vitro	50% Retention at 7.2 weeks in vitro	70% Retention at 6-8 weeks in vitro
<u>Cutting Options:</u>	Heat Loop or Pin Cutters	Scalpel	Heat Loop or Pin Cutters

OrthoSorb LS Traditional 510(k)

<u>Appearance:</u>	Clear, Yellow, or amber in color	Purple/Violet	Clear, Yellow, or amber in color
<u>Configuration:</u>	<p>OrthoSorb LS 1.3 mm Straight Pin Kit, 1 Pin) with instrumentation (2 k-wires, 1 pusher, 1 tube, 1 pin gauge)</p> <p>OrthoSorb LS 1.3 mm Straight Pin Kit 3 Pins with instrumentation (2 k-wires, 1 pusher, 1 tube, 1 pin gauge)</p> <p>OrthoSorb LS 2.0 mm Straight Pin Kit 1 Pin with instrumentation (2 k-wires, 1 pusher, 1 tube, 1 pin gauge)</p> <p>OrthoSorb LS 2.0 mm Straight Pin Kit 3 Pins with instrumentation (2 k-wires, 1 pusher, 1 tube, 1 pin gauge)</p> <p>OrthoSorb LS 1.3 mm Tapered Pin Kit with instrumentation (2 k-wires)</p>	<p>Straight Pin-Includes 1 tray Single tray includes 3 pins (40 mm x 1.3 mm diameter) with instrumentation</p> <p>Straight Pin-Includes 3 trays Each tray includes 1 pin (40 mm x 1.3 mm diameter) with instrumentation</p> <p>Straight Pin-Includes 1 tray Single tray includes 3 pins (40 mm x 2.0 mm diameter) with instrumentation</p> <p>Straight Pin-Includes 3 trays Each tray includes 1 pin (40 mm x 2.0 mm diameter) with instrumentation</p> <p>Straight Pin-Includes 1 tray-Single tray includes 2 pins (40 mm x 2.0 mm diameter) with instrumentation</p> <p>Tapered Pin-Includes 1 pin (50 mm x 1.3 mm diameter) with attached K-wire drill</p> <p>Arthroscopic Kit-Includes 1 tray Single tray includes 5 pins (40 mm x 1.3 mm diameter) with instrumentation</p>	Individually packaged
<u>Sterility:</u>	Ethylene Oxide Sterilization	Ethylene Oxide Sterilization	Ethylene Oxide Sterilization
<u>Packaging:</u>	Tyvek lid sealed to a PETG tray, outer foil pouch with a desiccant pouch, and a carton	Foil pouch, Paperboard, Tyvek-lid, PETG Tray	Tyvek lid sealed to a PETG tray, outer foil pouch with a desiccant pouch, and a carton

### **Section 13 – Proposed Labeling**

#### **Package Label**

A sample package label can be found in Tab A.

#### **Surgical Technique**

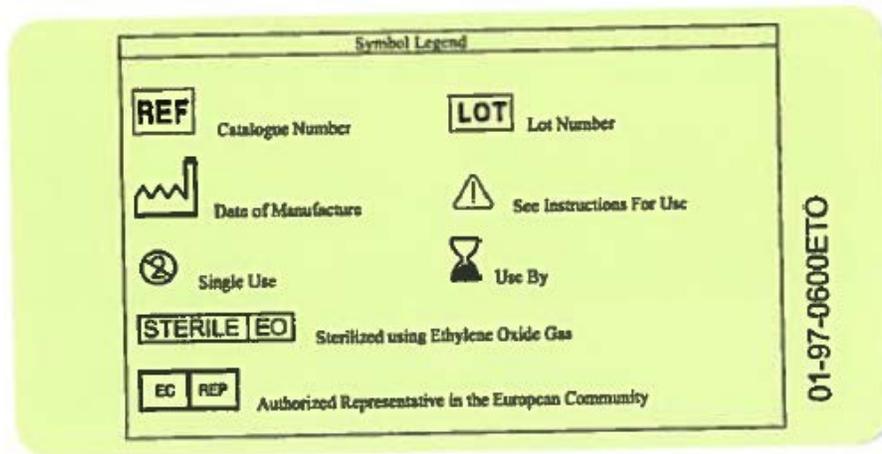
A draft surgical technique can be found in Tab B.

#### **Package Insert**

A draft Package Insert 01-50-1253 can be found in Tab C.

TAB A

<b>REF</b> 110010741	<b>LOT</b> TST123	 2019-03
<b>ORTHOSORB LS</b>		<b>QTY. 1 KIT</b>
<b>1.3 mm STRAIGHT PIN KIT, 1PIN</b>		
<b>PLLA/PGA PIN; SS &amp; POLYETHYLENE INSTRUMENTS</b>		
<b>KIT: 1Pin (1.3mm X 40mm), 2 K-Wires , 1 Inserter Tube, 1 Pusher Assembly, 1 Pin Gauge</b>		
<small>CAUTION: INNER STERILE MATERIAL IS MOISTURE SENSITIVE. ONCE THIS PACKAGE HAS BEEN OPENED, ITS CONTENTS MUST BE USED IMMEDIATELY. STORE AT OR BELOW ROOM TEMPERATURE. DO NOT EXPOSE TO TEMPERATURES AT OR ABOVE 120 DEGREE F OR 49 DEGREE C. DO NOT USE THIS PRODUCT IF THE INTERNAL TEMPERATURE INDICATOR IS BLACK OR MISSING. DO NOT RESTERILIZE.</small>		
		
	 MR MR SAFE	 STERILE EO
		 2014-03
 <b>BIOMET TRAUMA</b> 56 EAST BELL DRIVE P.O. BOX 587 WARSAW, IN 46581 USA	 <b>EC REP</b> <b>BIOMET U.K., LTD.</b> Waterton Industrial Estate Bridgend, South Wales CF31 3XA, UK	
		
		



# OrthoSorb<sup>®</sup> LS

## Resorbable Pins

(Now with LactoSorb<sup>®</sup>)

SURGICAL TECHNIQUE

### OrthoSorb LS Resorbable Pins

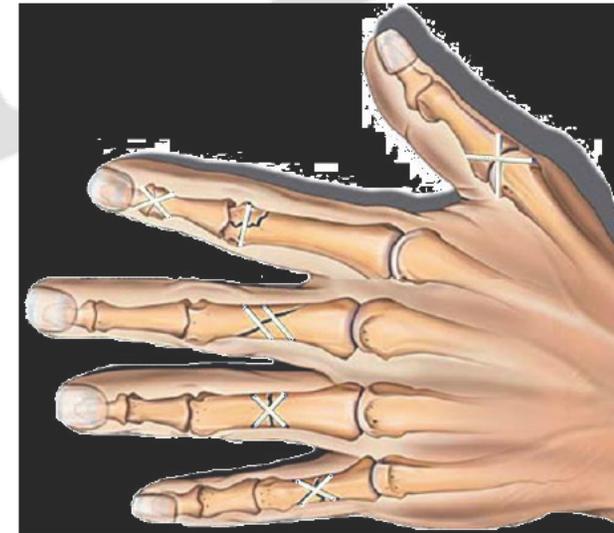
#### Material For Resorbable Fixa

OrthoSorb LS pins, are now made with LactoSorb<sup>®</sup>, a copolymer that is composed of polylactic acid and is 18% glycolic acid. These pins, and, are an alternative to metal fixation for selected applications.

- A gradual rate of absorption allows for an optimal transfer of support to the bone as it heals. The majority of the strength of the pin is gone at 12 weeks.
- Full hydrolysis in 9-12 months eliminates the need for a second surgery.
- OrthoSorb LS retains the majority of its strength through 6-8 weeks, providing fixation when required.
- Implants made of OrthoSorb LS are more rigid than poly-p-dioxanone implants and provide secure fixation while material strength is present.

#### OrthoSorb LS is offered in two different pin configurations:

- Original **Straight Pin** Kits in two diameters, 1.3 mm and 2.0 mm
- A 1.3 mm **Tapered Pin** design for through-and-through applications in the hand and foot..

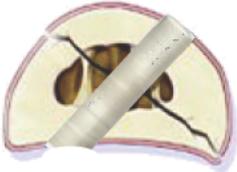


## Resorbable Pins

### Stages of Controlled Rate of Resorption

#### STAGE ONE:

Once in place, the OrthoSorb LS pin provides excellent support against the effects of shear and rotational forces during the first critical healing period of 6-8 weeks. Because the pin is made from LactoSorb (82% L-lactic acid and is 18% glycolic acid), the material is well accepted by the body.



Stage One

#### STAGE TWO:

As bone healing progresses, the OrthoSorb LS pin undergoes a planned reduction in strength. As it is resorbed, the pin gradually transfers the responsibility for bone fixation to the bone itself. Because its mass is resorbed slowly over a period of 9-12 months, the pin allows replacement bone growth to occur at a gradual and sustained rate.



Stage Two

#### STAGE THREE:

Within 9-12 months, the OrthoSorb LS pin is completely resorbed through hydrolysis. Healing has taken place without exposed protuberant pins or additional surgery to remove metallic implants. Consequently, there is less trauma to patients and fewer opportunities for pin-tract infection.



Stage Three

## Surgical Technique

### STRAIGHT PIN TECHNIQUE

1. Place the contents of the kit in the sterile field.
2. Select a K-wire and use it to drill through the bone fragment into the underlying bone to the desired depth. If introducing more than one OrthoSorb LS pin, the holes should be drilled at angles rather than parallel to one another (Figure 1).
3. Use the gauging probe as a depth gauge by introducing the hooked end of the gauging probe into the previously drilled hole. Slide the disk to the bone fragment and remove the gauging probe (Figure 2).
4. Insert the straight end of the gauging probe into either end of the applicator tube, and push in as far as the disk. Using either a pin cutter, or a HeatLoop, cut off and discard the portion of the OrthoSorb LS pin that protrudes from the applicator tube (Figure 3).
5. Place the plunger on the cut end of the OrthoSorb LS pin. Apply the opposite end of the applicator to the drilled hole, in the same orientation as the hole, and press the pin into the canal using the pusher, or gently tap the proximal knob of the plusher with a small mallet. The pin should be recessed approximately 1mm below the surface of the fragment.

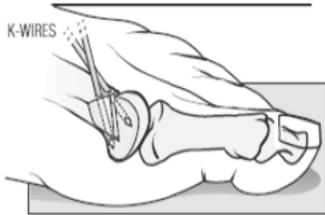


Figure 1

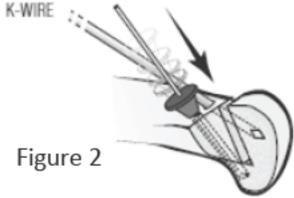


Figure 2

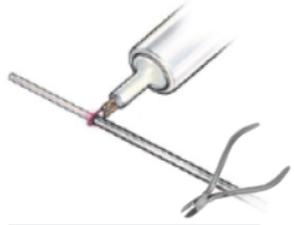


Figure 3

Note: The number of pins used should be based upon the size and position of the fragment. OrthoSorb LS pins should not be removed once healing has occurred. After undergoing hydrolysis, the pins should be removed from the bone fragment approximately 1 year from insertion.

**TAPERED PIN TECHNIQUE**

1. Place the contents of the kit in the sterile field (Figure 1).
2. Select a K-wire and drill through the bone with a pin driver until the K-wire has been completely drilled through the far cortex of the bone (Figure 2). Remove the K-wire, noting the location of the hole with a marker (Figure 3).
3. Manually place the smallest diameter end of the OrthoSorb LS Tapered Pin through the hole and push it into the hole until it becomes wedged and can no longer advance (Figure 4). Then from the other side of the bone, gently pull the pin with your fingers (Figure 5), or with forceps (Figure 6) until the pin is securely wedged into its final position.
3. Trim both ends of the OrthoSorb LS Tapered Pin utilizing pin cutters or a Heat Loop (Figure 7).

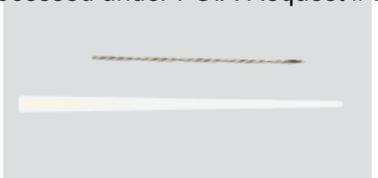


Figure 1



Figure 2

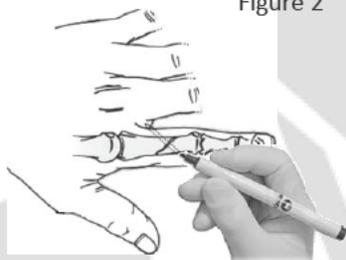


Figure 3

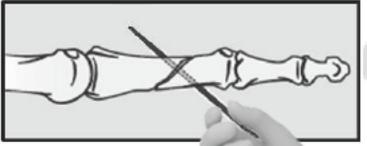


Figure 4

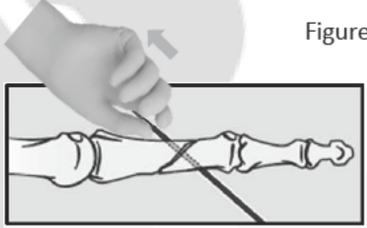


Figure 5

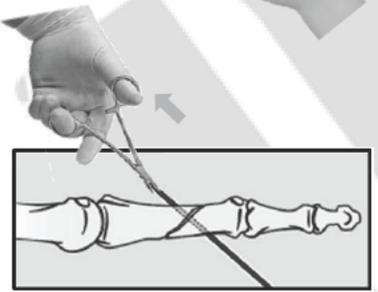


Figure 6

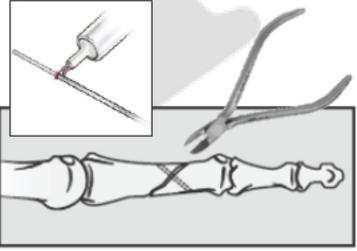


Figure 7

**ADDITIONAL PRODUCT INFORMATION**

Handling and Care of Product

**CAUTION:**  
STORE AT OR BELOW ROOM TEMPERATURE. DO NOT EXPOSE PRODUCT TO TEMPERATURES GREATER THAN 120° F OR 49°C.

Resorbable implants are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date.

Product Offering

Cat. No.	Description
110010741	OrthoSorb LS 1.3 mm Straight Pin Kit 1 Pin, 1 Pack
110010742	OrthoSorb LS 1.3 mm Straight Pin Kit 3 Pins, 1 Pack
110010743	OrthoSorb LS 2.0 mm Straight Pin Kit 1 Pin, 1 Pack
110010744	OrthoSorb LS 2.0 mm Straight Pin Kit 3 Pins, 1 Pack
110010745	OrthoSorb LS 1.3 mm Tapered Pin Kit

Additional Instrumentation:

905414	Heat Loop
--------	-----------

**Essential Product Information: INDICATIONS**

The OrthoSorb® LS Resorbable Bone Pins are indicated for use in:

- 1.) To fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals;
- 2.) For fixation of inherently stable osteotomies of the great toe and first metatarsal and intramedullary stabilization of joint arthroplasty (resection) for the treatment of lesser toe deformities.
- 3.) Used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.

1.35mm [Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118](mailto:Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118)

## TAB C

 **Biomet Trauma**  
56 East Bell Drive  
P.O. Box 587  
Warsaw, IN 46581-0587 USA

**01-50-1253**

## Revision A

Date: 2014-02



### **BIOMET® ORTHOSORB LS RESORBABLE FIXATION DEVICES**

#### **ATTENTION OPERATING SURGEON**

#### **DESCRIPTION**

Biomet® OrthoSorb LS resorbable fixation devices include straight and tapered pins. Biomet® OrthoSorb LS resorbable fixation devices are made of a resorbable copolymer, polyester derivative of L-lactic and glycolic acids. Poly L-lactic / polyglycolic acid copolymer degrades and resorbs *in-vivo* by hydrolysis into L-lactic and glycolic acids which are then metabolized by the body.

#### **MATERIALS**

Poly-L Lactic Acid/ Polyglycolic Acid  
Stainless Steel  
Polyethylene

#### **INDICATIONS**

- 1.) To fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals;
- 2.) For fixation of inherently stable osteotomies of the great toe and first metatarsal and intramedullary stabilization of joint arthroplasty (resection) for the treatment of lesser toe deformities.
- 3.) Used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.

#### **CONTRAINDICATIONS**

Use is contraindicated in cases where:

1. Conservative (closed) treatment is appropriate
2. Pressure osteosynthesis is desired
3. Fragments are subjected to tension stress
4. Overt infection is present
5. Patient has a history of adverse reactions to resorbable materials (e.g. resorbable sutures).
6. Patients with mental or neurologic conditions are unwilling or incapable of following postoperative care instructions.
7. Patient with conditions including, blood supply limitations, insufficient quantity or quality of bone stock or latent infection.
8. Load bearing procedures

#### **WARNINGS**

Internal fixation devices aid the surgeon in the alignment and stabilization of skeletal fractures and provide a means of fracture management in reconstructive surgical applications. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of nonunion, delayed union, or incomplete healing. Internal fixation devices are internal splints that align the fracture until normal healing occurs. The size and shape of bones and soft tissue place limitation on the size and strength of implants. If there is delayed union or nonunion of bone in the presence of weight bearing, or load bearing, the implant could eventually break. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the fracture site be maintained until firm bone union (confirmed by clinical and radiographic examination) is established. Surgical implants are subject to repeated stresses in use, which can result in fatigue fracture. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the service life of the implant. The surgeon must be thoroughly

knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and chemical aspects of the surgical implants.

1. Correct selection of the implant is extremely important. The potential for success in fracture fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal healthy bone. These devices are not designed to withstand the unsupported stress of full weight bearing, or load bearing.
2. Improper selection, placement, positioning, and fixation of the device can lead to failure of the device or the procedure. The surgeon is to be familiar with the devices, the method of application and the surgical procedure prior to performing surgery. The surgeon must select a type or types of internal fixation devices appropriate for treatment.
3. These devices are resorbable and do not provide permanent fixation. Do not use in procedures where a permanent implant is needed.
4. Correct handling of implants is extremely important. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Intraoperative fracture of devices can occur if excessive force (torque) is applied while seating.
5. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure requiring additional surgery and device removal.
6. Do not use if there is loss of sterility of the device. Discard and do not use previously opened or damaged devices. Use only devices that are packaged in unopened or undamaged containers. Once the foil barrier has been breached, the device should be used promptly or discarded.
7. When resorbable fixation devices are used to aid in the alignment and stabilization of bones in the hand or foot, appropriate immobilization and rehabilitation is necessary for the desired outcome.
8. Patients that engage in stressful physical activities are to be warned that injury at or near the implant site can lead to failure of the device and/or the treatment.
9. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture management. Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing.
10. Noncompliance with postoperative instructions could lead to failure of the device, which could require additional surgery and device removal.
11. Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device. Sufficient bone quantity and quality are important to adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.
12. These devices should not be used for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
13. Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.
14. Device is single use only. After use, the device may be a potential biohazard. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.
15. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

#### **PRECAUTIONS**

1. Do not use Biomet® OrthoSorb LS resorbable implants with resorbable implants made by other manufacturers due to the probability of incompatible fits, sizes and rates of resorption.
2. The OrthoSorb LS 1.3mm and 2.0mm Straight and 1.3mm Tapered Resorbable Pins with Applicator Kits are intended for use with the (2) 1.3mm or 2.0mm K-wires provided. If a K-wire of a different diameter is used, the fit and security of the Resorbable Pins within the bone may be compromised. Under no circumstances should K-wires other than respectively 1.3mm (0.051 in.) and 2.0mm (0.078 in.) in diameter be used.
3. Instruments are available to aid in the accurate implantation of Biomet® resorbable pins. Intraoperative fracture of instruments has been reported, however the surgical instruments offered in the applicator kit are provided sterile and are intended for single use only. Kit instruments should be discarded after surgery and are not to be reused.
4. The patient is to be made aware of the surgical risks and possible adverse effects prior to surgery, and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.
5. All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.



**Biomet® OrthoSorb LS Implants in the Magnetic Resonance (MR) Environment**

OrthoSorb LS implants are made of a resorbable copolymer, polyester derivative of L-lactic and glycolic acids. These materials are non-conducting and nonmagnetic. Therefore, in accordance with the definition stated in ASTM F-2503-08, Standard Practice for Marking Devices and Other Items for Safety in the Magnetic Resonance Environment, the devices are determined to be “MR Safe –an item that poses no known hazards in all MR environments.”

**POSSIBLE ADVERSE EFFECTS**

1. Infection can lead to failure of the procedure.
2. Neurovascular injuries can occur due to surgical trauma.
3. Bending, fracture, loosening, rubbing and migration of the devices can occur as a result of excessive activity, trauma or load bearing.
4. Implantation of foreign materials can result in an inflammatory response or allergic reaction.
5. Nonunion, delayed union, or incomplete healing which may lead to breakage of the implant or failure of the treatment.
6. Pain, discomfort, or abnormal sensation due to the presence of the device.
7. Disfigurement may occur due to improper alignment of bone fragments.
8. Necrosis of Bone.
9. Inadequate healing.

**STERILITY**

Resorbable implants are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date. Single Use Only. Do Not Reuse. Do not use from an opened or damaged package.

**STORE AT OR BELOW ROOM TEMPERATURE. DO NOT EXPOSE PRODUCT TO TEMPERATURES GREATER THAN 120° F OR 49°C.**

**CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968.

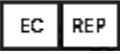
All trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

**CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.**

EC	REP	Authorized Representative:	Biomet U.K., Ltd. Waterton Industrial Estate Brigend, South Wales CF3 3XA, U.K.
----	-----	----------------------------	--



Symbol Legend	
	Manufacturer
	Date of manufacture
	Do not reuse
	Do not resterilize
	Caution, see instructions for use

	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using steam or dry heat
	MR Safe
	Use by date
	WEEE device
	Catalogue number
	Batch code
	Flammable
	Authorized representative in the European Community

**Section 14 – Sterilization and Shelf Life**

***Sterilization***

OrthoSorb S will be sterilized by Ethylene Oxide (ETO). The sterilization process validation is to be in accordance to the principle outlined in BS EN ISO 11135-1, Method C: Half Cycle. Product shall not be commercialized until the validations are complete.

This same sterilization configuration is currently in use for the LactoSorb Bone Pins cleared in K990291.

Parameters	
Precondition Parameters	(b)(4)
Process Temperature	
Initial Vacuum pressure	
Add Humidity	
Humidity Dwell Time	
Gas Pressure	
Gas Dwell Time	
Gas Dwell Temperature	
After Vacuum Pressure	
Release Pressure	
Aeration Parameter	

Gas Type: Ethylene Oxide (ETO)

Residuals: meet the AAMI/ANSI/ISO 10993-7

Standard	EO Limits	ECH Limits
ISO 10993-7	<0.1 mg/day	<0.4 mg/day
	<4 mg/first 24 hr.	<9 mg/first 24 hr.
	<60 mg/30 days	<60 mg/30 days
	2.5 g/lifetime	<10 g/lifetime

Sterility Assurance Level: 10<sup>-6</sup>

Sterility Validation Method: EN ISO 11135-1:2007

Pyrogenicity: No claims will be made

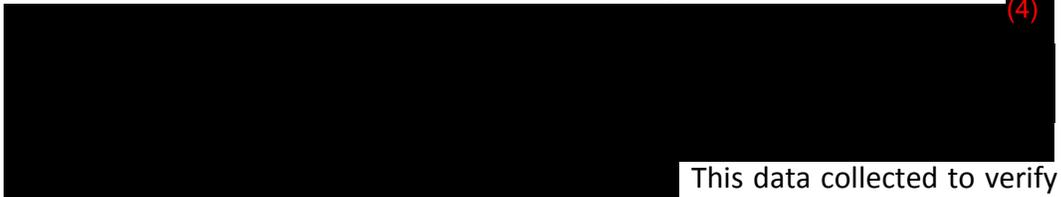
***Packaging Description***

The OrthoSorb LS Bone pin kits including the LactoSorb bone pins and associated disposable instruments are packaged in a PETG tray with retainer and sealed Tyvek lid. The PETG Tray and desiccant packet are then sealed inside a foil pouch and a temperature indicator label affixed to the exterior of the foil pouch. The desiccant packet serves to absorb errant moisture present in the foil pouch to prevent degradation of the new Orthosorb LS implants on the shelf. The temperature indicator label affixed to the exterior of the foil pouch serves as a means to detect if the implant has been exposed to temperatures above 49°C,

and the integrity of the material becomes compromised. The OrthoSorb LS label and package insert both states "Store at or below room temperature. Do not expose to temperatures above 120°F or 49°C. Do not use product if indicator dot is black". This same packaging configuration exists in the LactoSorb Bone Pins, K990291.

***Shelf Life / Aging***

The predicate LactoSorb device material properties were evaluated to verify material stability to 5 years after the manufacturing date when packaged in a foil pouch with desiccant and maintained at a temperature below 49 °C. (b) (4)



This data collected to verify the 5 year shelf-life was taken on the predicate LactoSorb Bone Pins (K990291) devices that were in the field. Due to the material composition and the packaging being the same, the shelf-life of the new OrthoSorb LS Bone Pin Kit is supported for 5 years.

The disposable stainless steel instruments in the OrthoSorb LS Bone Pin Kits are equivalent in both composition and application to those cleared in the DePuy OrthoSorb Bone Pin Kits (K901456 and K111077) and Biomet LactoSorb Bone Pins (K990291). Both of these predicate devices are sterilized via Ethylene Oxide and the LactoSorb Bone Pins have identical packaging to the proposed OrthoSorb LS Bone Pin Kits. Both of these products have 5 year shelf-life, thereby supporting the stability of the disposable Stainless Steel instruments in the OrthoSorb LS Bone Pin Kit.

High Density Polyethylene (HDPE) used for the disc on the OrthoSorb LS Bone Pin disposable depth gauge is equivalent to the HDPE used in the disposable depth gauge disc in the Biomet LactoSorb Bone Pins<sup>1</sup>. Additionally, the OrthoSorb LS Bone Pin Kit and Biomet LactoSorb Bone Pins have identical packaging and are terminally sterilized by EtO. The 5 year shelf-life of the OrthoSorb LS Bone Pin kit depth gauge is supported by the stability and lengthy clinical history (launched in 2004) of the LactoSorb Bone Pins with no complaints related to the HDPE disc on the disposable depth gauge.

Due to the equivalency of the raw materials, packaging, and manufacturing of the OrthoSorb LS Bone Pin Kit to those of the LactoSorb Bone Pins (K990291) and OrthoSorb (K901456 and K111077), the shelf-life of the new OrthoSorb LS Bone Pin Kit is supported for 5 years.

1. Instrument added to the system via internal documentation post initial clearance

## Section 15 – Biocompatibility

The OrthoSorb LS bone pin kits are composed of Lactosorb , PLGA (82% PLLA-18% PGA) Bone Pins (1.3mm straight, 1.3mm tapered, and 2.0mm straight) which are permanent implants. OrthoSorb LS is manufactured from a resorbable polymer, PLGA (82% PLLA- 18% PGA). The biocompatibility of these materials and manufacturing processes has been assessed in accordance ISO 10993-1: “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process” for the anticipated duration of contact with muscle/bone.

The raw material used to fabricate OrthoSorb LS is LactoSorb L1 resin, 82%PLLA/18%PGA, manufacturing process of extrusion, machining, cleaning and ETO Sterilization. The LactoSorb L1 resin used to produce the bone pin implants in the OrthoSorb LS bone pin kits have a well-established clinical history and biocompatibility.

**Table 3: Implants and Applicator Kit Product offerings, Materials, Standards**

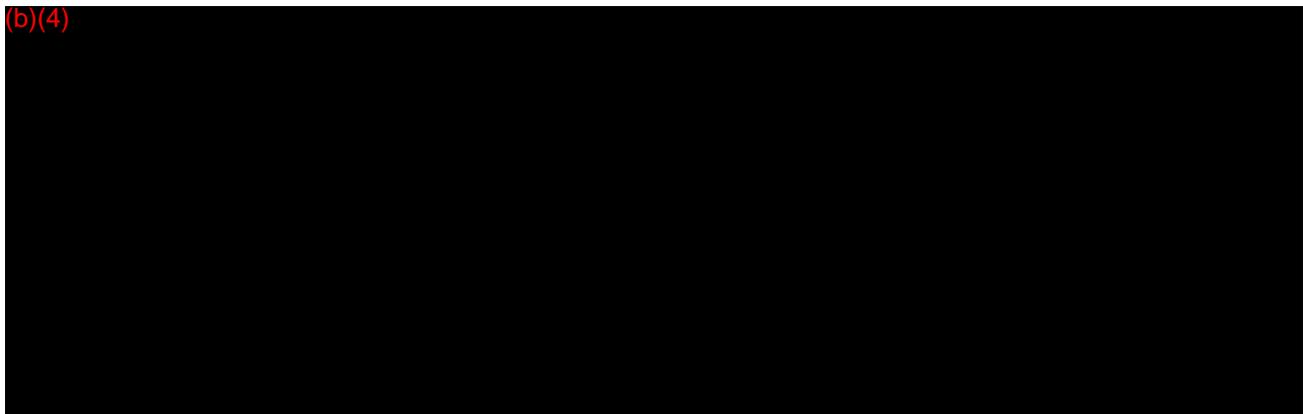
<b><u>Product Number</u></b>	<b><u>Description</u></b>	<b><u>Implant Material:</u></b>	<b><u>Implant Material Standard:</u></b>
110010741	OrthoSorb LS 1.3 mm Straight Pin Kit 1 Pin, 1 Pack	82% PLLA-18% PGA copolymer (PLGA)	ASTM F2579
110010742	OrthoSorb LS 1.3 mm Straight Pin Kit 3 Pins, 1 Pack	82% PLLA-18% PGA copolymer (PLGA)	ASTM F2579
110010743	OrthoSorb LS 2.0 mm Straight Pin Kit 1 Pin, 1 Pack	82% PLLA-18% PGA copolymer (PLGA)	ASTM F2579
110010744	OrthoSorb LS 2.0 mm Straight Pin Kit 3 Pins, 1 Pack	82% PLLA-18% PGA copolymer (PLGA)	ASTM F2579
110010745	OrthoSorb LS 1.3 mm Tapered Pin Kit	82% PLLA-18% PGA copolymer (PLGA)	ASTM F2579

The raw materials that are used in the production of the disposable instruments that are packaged in the OrthoSorb LS straight pins and tapered pin kits are: Stainless Steel – 316LVM, 302, 304, and HDPE. The disposable instruments are manufactured from stainless steel (316-LVM, 304, and 302 per ASTM –F899, Standard Specification for Wrought Stainless Steels for Surgical Instruments) and HDPE. The various disposable instruments have direct contact but have a contact time of less than 24 hours of contact duration. The instruments included in the OrthoSorb LS kits include: K-Wires, Depth Gauge, Tubes, and a Pusher. The manufacturing processes, machining or injection molding, cleaning, and ETO sterilization used to produce the disposable instrumentation in the OrthoSorb LS bone pin kits have a well-established clinical history and biocompatibility for use in direct contact with the patient for less than 24 hours.

**Table 4:** Specialized Instrumentation (Bone contact, External communicating, Direct Contact, Limited Contact, ≤24 hours)

<b>Product Number:</b>	<b>Description:</b>	<b>Material:</b>	<b>Standard:</b>
110017450	1.3mm K-wire	(b)(4)	ASTM F899
110017416 110017413	1.3mm Pin Gauge		ASTM F899 (for 302 SS)
110017442	1.3mm Pusher		ASTM F899
110017446	1.3mm Tube		ASTM F899
110017451	2.0mm K-wire		ASTM F899
110017458	2.0mm Pusher		ASTM F899
110017452	2.0mm Tube		ASTM F899

(b)(4)

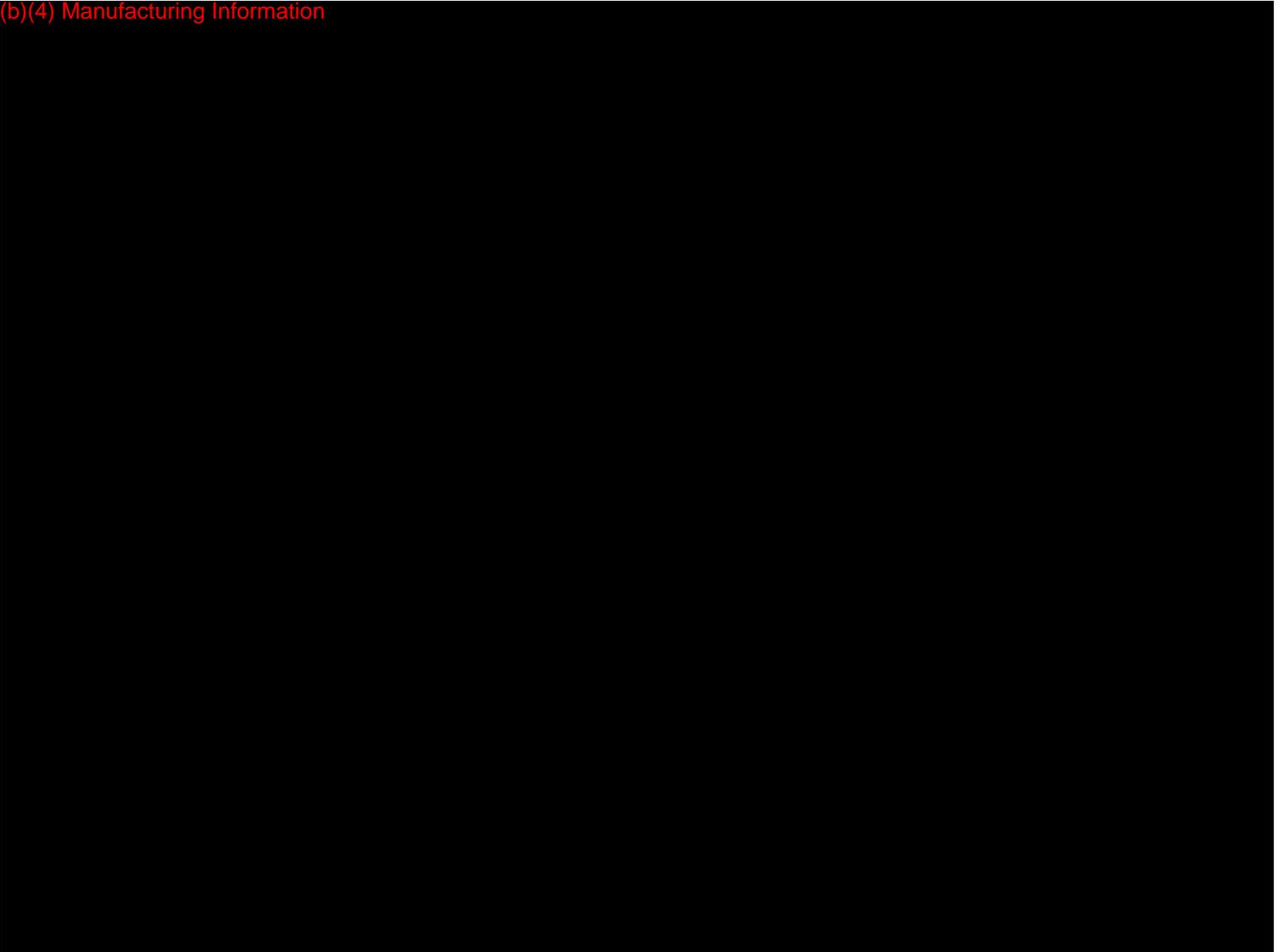


1. For this category of instrument based on contact and duration, although cytotoxicity and sensitization data is not available, implantation testing and acute systemic toxicity provide biocompatibility data above the requirements demonstrating the biocompatibility of this material.





(b)(4) Manufacturing Information



Therefore, it is concluded that the OrthoSorb LS Bone Pin implants are biocompatible for permanent implantation and the disposable instruments are biocompatible for temporary less than 24 hours contact duration with bone and tissue.

## **Section 16 – Software**

This section is not applicable because OrthoSorb LS does not contain software.





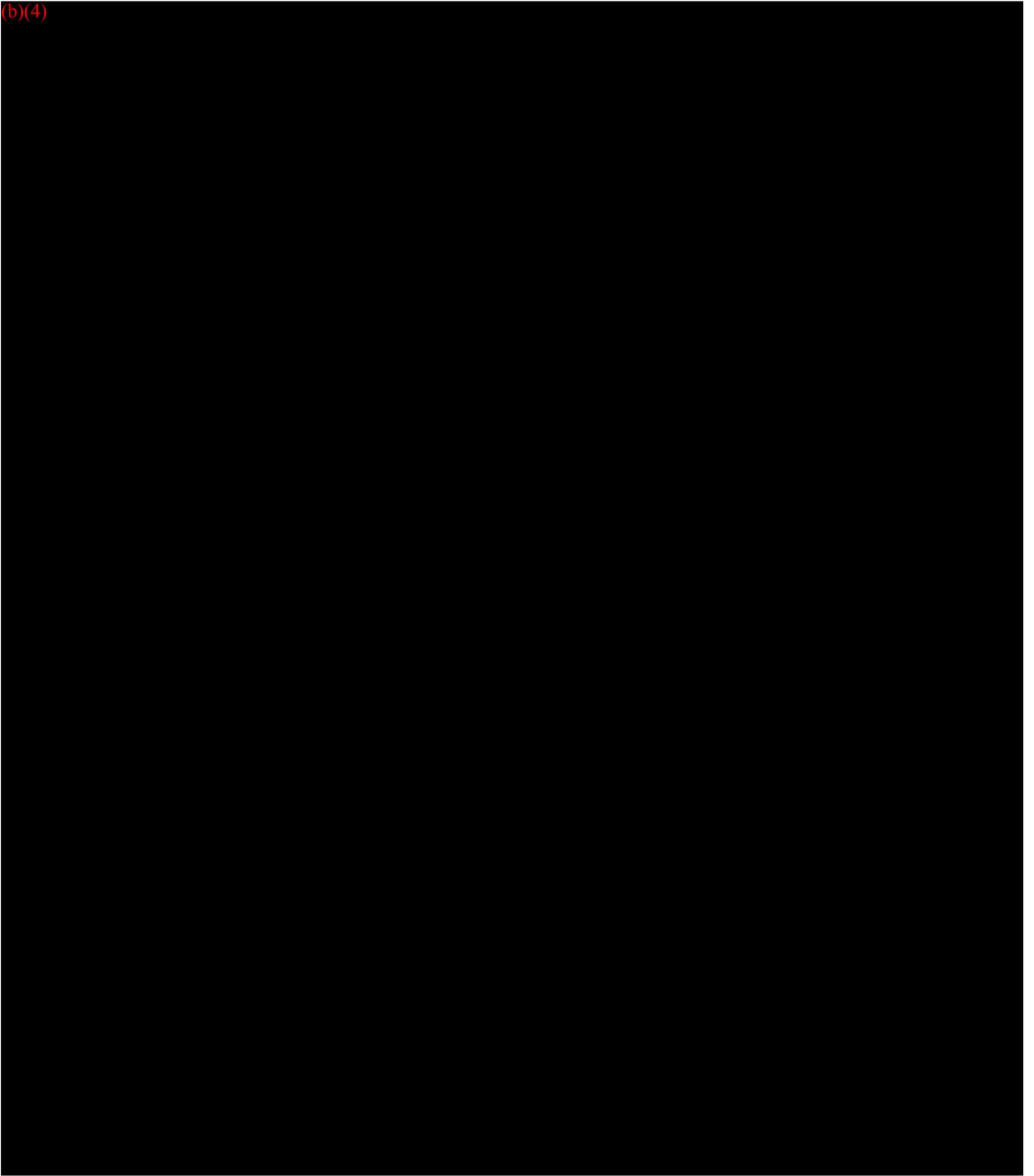
Table 1. Literature review for MR Safety and Compatibility.

Reference
ASTM F2052 - 06e1 "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment"
ASTM F2119 - 07(2013) "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants"
ASTM F2213 - 06(2011) "Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment"
ASTM F2182 - 11a "Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging"
ASTM F2503 - 08 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"
A Primer on Medical Device Interactions with MRI Systems; <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107721.htm#overview">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107721.htm#overview</a> ].
FDA Public Health Notification: MRI-Caused Injuries in Patients with Implanted Neurological Stimulators, May 10 2005
FDA Public Health Notification: MRI-Related Death of Patient With Aneurysm Clip, Nov. 25, 1992.
ISO/TS 10974:2012(E), " Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device", 2012
OECD Health Data 2011. <a href="http://stats.oecd.org/Index.aspx?DataSetCode=HEALTH_PROC">http://stats.oecd.org/Index.aspx?DataSetCode=HEALTH_PROC</a>
2007 MRI Market Summary Report Sections A & B. IMV, 1400 EAST TOUHY AVE, SUITE 250, DES PLAINES, IL 60018
Brendon Nafziger, "Is 7-Tesla MRI where 3-Tesla was 10 years ago?", January 12, 2012, dotmed, <a href="http://www.dotmed.com/news/story/17820">http://www.dotmed.com/news/story/17820</a> .
Yacoub E, Shmuel A, Pfeuffer J, Van De Moortele PF, Adriany G, Andersen P, Vaughan JT, Merkle H, Ugurbil K, Hu X. "Imaging brain function in humans at 7 Tesla". Magn Reson Med 2001;45:588-594.
Y. Liu, J. Shen, W. Kainz, S. Qian, W. Wu and J. Chen, " Numerical investigations of MRI RF field induced heating for external fixation devices", BioMedical Engineering OnLine 2013, 12:12, <a href="http://www.biomedical-engineering-online.com/content/12/1/12">http://www.biomedical-engineering-online.com/content/12/1/12</a>
H. Muranaka, T. Horiguchi, Y. Ueda, S. Usui, N. Tanki, O. Nakamura, "Evaluation of RF Heating on Hip Joint Implant in Phantom during MRI Examinations", Japanese Journal of Radiological Technology, Vol. 66 (2010) No. 7 P 725-733.
J.A. Nyenhuis and C.R. Miller, "Calculation of Heating of Passive Implants by the RF Electromagnetic Field in MRI", General Assembly and Scientific Symposium, 2011 XXXth URSI, 2011

<p>E. Mattei, M. Triventi, G. Calcagnini, F. Censi, and P. Bartolini, "Radiofrequency Dosimetry in Subjects Implanted with Metallic Structures Undergoing MRI: a Numerical Study", <i>Am. J. Biomed. Sci.</i> 2009, 1(4), 373-384.</p>
<p>I. B. Akca, O. Ferhanoglu, C. J. Yeung, S. Guney, T. O. Tasci, E. Atalar," Measuring Local RF Heating in MRI: Simulating Perfusion in a Perfusionless Phantom", <i>JOURNAL OF MAGNETIC RESONANCE IMAGING</i> 26:1228–1235 (2007).</p>
<p>R. Luechinger, V. A. Zeijlemaker, F. Duru3, P. Boesiger," RF-heating effects on coated wires and pacemaker leads at 1.5T and 3.0T", <i>Proc. Intl. Soc. Mag. Reson. Med.</i> 14 (2006)</p>
<p>S.M. Park, R. Kamondetdacha, J. A. Nyenhuis," Calculation of MRI-Induced Heating of an Implanted Medical Lead Wire With an Electric Field Transfer Function", <i>JOURNAL OF MAGNETIC RESONANCE IMAGING</i> 26:1278–1285 (2007).</p>
<p>A. Completo, M. Coutinho, M. Schiller, A. Ramos, C. Relvas, J. A. Simoes," A Device to Control Implant and Bone-Cement Temperatures in Cemented Arthroplasty", <i>Journal of Medical Devices</i> MARCH 2012, Vol. 6 / 014503-1.</p>
<p>C.C Huang , Y.C. Liu , L. W. Chen, Y. C. Chen," Temperature rise of alveolar bone during dental implant drilling using the finite element simulation", <i>Life Science Journal</i>, Vol , No , 2010</p>
<p>M.T. Hillerya, I. Shuaibb," Temperature effects in the drilling of human and bovine bone", <i>Journal of Materials Processing Technology</i> 92-93 (1999) 302-308.</p>
<p>S.J. Kim, J. Yoo, Y.S. Kim, S. W. Shin," Temperature change in pig rib bone during implant site preparation by low-speed drilling", <i>J Appl Oral Sci.</i> 2010;18(5):522-7</p>
<p>S. H. Tehemar, "Factors Affecting Heat Generation During Implant Site Preparation: A Review of Biologic Observations and Future Considerations", <i>INT J ORAL MAXILLOFAC IMPLANTS</i> 1999;14:127–136.</p>

**Section 18 - Performance Testing – Bench**

(b)(4)



























**Section 19 – Performance Testing – Animal**

This section is not applicable because there was no animal testing performed with OrthoSorb LS.

## **Section 20 – Performance Testing – Clinical**

This section is not applicable because clinical studies were not conducted for this submission.

JUL 12 2011 K111077  
p1/2

**510(k) Summary**

**Submitted by:** DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
Warsaw, IN 46581  
Phone: (305) 269-6386  
Fax: (305) 269-6441

**Contact Person:** Suzana Otaño, Project Manager, Regulatory Affairs

**Date Prepared:** April 14, 2011

**General Provisions** The name of the device is:

Proprietary Name	Common or Usual Name
ORTHOSORB® Resorbable Pins	Pin, Fixation, Resorbable, Hard Tissue

**Name of Predicate Devices** The device is substantially equivalent to the currently marketed ORTHOSORB Resorbable Pin, K901456.

**Classification** Class II, Regulation Number 21 CFR 888.3040, Product Code OVZ

**Performance Standards** Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act for these devices.

**Device Description** The ORTHOSORB 1.3mm and 2.0mm Resorbable Pins are made from poly-p-dioxanone and are available in 1.3mm and 2.0mm diameters and 40mm and 50mm lengths with their accompanying instrumentation.

**Indications for Use** The ORTHOSORB Resorbable pin are indicated for use to fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals; or for fixation of inherently stable osteotomies of the great toe and intramedullary stability of joint arthroplasty (resection) for the treatment of lesser toe deformities. The Resorbable Pin can be used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.

**Technological Characteristics** The technological characteristics of the ORTHOSORB Resorbable pins that are the subject of this submission remain unchanged from the predicate device in terms of design, material and performance.

211107  
p/2

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**Summary of  
Substantial  
Equivalence**

The ORTHOSORB Resorbable pins that are the subject of this submission are equivalent to the predicate device. The technological characteristics are identical. Based on material, the pins are considered MR Safe as defined in ASTM F2503.

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

JUL 12 2011

DePuy Orthopaedics, Inc.  
% Ms. Suzana Otaño  
700 Orthopaedic Drive  
Warsaw, IN 46581-0988

Re: K111077  
Trade/Device Name: ORTHOSORB Resorbable Pin  
Regulation Number: 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: OVZ  
Dated: April 14, 2011  
Received: April 18, 2011

Dear Ms. Otaño,

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

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

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

Page 2 – Ms. Suzana Otaño

device-related adverse events) (21 CFR 803); 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. 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,



*f* Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number: K111077

Device Name: **ORTHOSORB Resorbable Pin**

Indications For Use:

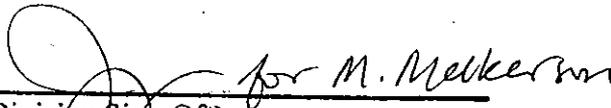
The ORTHOSORB Resorbable pin are indicated for use to fix in place small bony or chondral fragments in the knee and hand where such fragments are not in tension, as in the case of osteochondritis dissecans or fractures of the phalanges and metacarpals; or for fixation of inherently stable osteotomies of the great toe and intramedullary stability of joint arthroplasty (resection) for the treatment of lesser toe deformities. The Resorbable Pin can be used to provide additional support in cases of finger joint fusion and digit replantation where standard fixation or support techniques are also employed.

Prescription Use X AND/OR Over-the-Counter \_\_\_\_\_  
(Per 21 CFR 801 Subpart D) (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)

Page 1 of 1

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

510(k) Number K111077

3/23/99

K99629

### 510 (K) Summary of Safety and Effectiveness

Submitter: Biomet, Inc.  
P.O. Box 587  
Airport Industrial Park  
Warsaw, Indiana 46581-0587

Contact Person: Michelle L. McKinley

Product Code: 87HTY

Device Name: LactoSorb® Bone Pin

The LactoSorb® Bone Pin is indicated for use in the presence of appropriate immobilization in the following procedures:

1. correction of hallux valgus (bunion)
2. repair of metacarpal and phalangeal fusion and fractures

The LactoSorb® Bone Pin is made of bioresorbable and biocompatible polymers that have been used in surgical procedures for numerous years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid (PLLA/PGA) copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids, which are then metabolized by the body.

The effectiveness of the LactoSorb® Bone Pin was determined by In VITRO mechanical comparative testing to currently marketed resorbable pins. The tests showed that the LactoSorb® pins demonstrated adequate initial strength and retained at least 80% of that strength at 8 weeks. In the same test environment at eight weeks, the comparative pins exhibited little or no strength.

In summary, the LactoSorb® Bone Pin is safe and effective for metacarpal and phalangeal repair. Mechanical testing demonstrated the Lactosorb® Bone Pin to be as effective or better than comparative resorbable bone pins.

00004



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 23 1999

Ms. Michelle L. McKinley  
Regulatory Specialist  
Biomet, Inc.  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K990291  
Trade Name: LactoSorb® Bone Pin  
Regulatory Class: II  
Product Codes: HTY and MAI  
Dated: January 22, 1999  
Received: January 29, 1999

Dear Ms. McKinley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general 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.

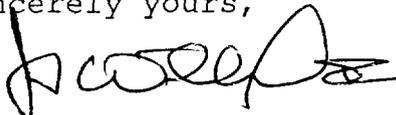
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Michelle L. McKinley

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

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

Enclosure

510 (k) NUMBER (IF KNOWN): K990291

DEVICE NAME: LactoSorb® Bone Pin

INDICATIONS FOR USE:

The LactoSorb® Bone Pin is indicated for use in the presence of appropriate immobilization in the following procedures:

1. correction of hallux valgus (bunion)
2. repair of metacar pal and phalangeal fusion and fractures

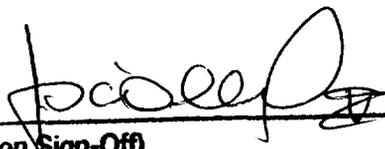
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter-  
(Optional Format 1-2-96)

  
 (Division Sign-Off)  
 Division of General Restorative Devices  
 510(k) Number K990291

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OrthoSorb LS Traditional 510(k)