U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K062789 - 168 pages
COMPANY:	SYNTHES (USA) (SYNTHES)
PRODUCT:	PLATE, BONE (JEY)
SUMMARY:	Product: SYNTHES (USA) RAPID RESORBABLE FIXATION SYSTEM
DATE REQUESTED:	Aug 31, 2016
DATE PRINTED:	Aug 31, 2016
Note:	Printed

SYNTHES®

K062789

3.0 Summary of Safety and Effectiveness Information

SPONSOR:	Synthes (USA) 1302 Wrights Lane East West Chester, PA 19308 (610) 719-5000

FEB 27 2007

DEVICE NAME:	Synthes (USA) Rapid Resorbable Fixation System
CLASSIFICATION:	Class II, §872.4760 - Bone Plate Class II, §888.3030 – Screw Fixation, Intraosseous Class II, §882.5360 – Cranioplasty plate fastener
PREDICATE DEVICE:	Synthes (USA) Rapid Resorbable Tack System Synthes (USA) Poly (L-Lactide-co-Glycolide) Resorbable Fixation System Synthes (USA) Rapid Resorbable Cranial Clamp Biomet, Inc., Lactosorb Trauma Plating System
DEVICE DESCRIPTION:	The Synthes Rapid Resorbable Fixation System consists of Plates, Meshes, Sheets, Screws and Tacks. The system is provided in a variety of shapes and sizes and, when used in conjunction with resorbable screws, the system provides fixation and aids in the alignment and stabilization of craniofacial bones. To facilitate shaping to the contours of the anatomy, the thermoplastic implants may be heated above the glass transition temperature of 55°C or they may be cut to the desired shape.
INTENDED USE:	The Synthes (USA) Rapid Resorbable Fixation System is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations. In addition, resorbable meshes, sheets, screws and tacks may be used in non-load bearing applications for maintaining the relative position of, and /or containing, bony fragments, bone grafts, (autograft or allograft), or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.
CONTRAINDICATIONS:	These devices are not intended for use in load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. The Synthes Rapid Resorbable System is not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.
SUBSTANTIAL EQUIVALENCE	Comparative information presented supports substantial equivalence.
MATERIAL:	Poly (L-lactide-co-glycolide)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jeffrey L. Dow
Director, Regulatory Affairs
Synthes (USA)
1230 Wilson Drive
West Chester, Pennsylvania 19380

FEB 27 2007

Re: K062789
Trade/Device Name: Synthes (USA) Rapid Resorbable Fixation System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: February 2, 2007
Received: February 5, 2007

Dear Mr. Dow:

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

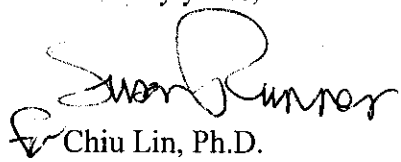
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K062789

Device Name: Synthes (USA) Rapid Resorbable Fixation System

Indications:

The Synthes (USA) Rapid Resorbable Fixation System is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations. In addition, resorbable meshes, sheets, screws and tacks may be used in non-load bearing applications for maintaining the relative position of, and /or containing, bony fragments, bone grafts, (autograft or allograft), or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

Susan Runner

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

K062789

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jeffrey L. Dow
Director, Regulatory Affairs
Synthes (USA)
1230 Wilson Drive
West Chester, Pennsylvania 19380

FEB 27 2007

Re: K062789
Trade/Device Name: Synthes (USA) Rapid Resorbable Fixation System
Regulation Number: 872.4760
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Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Susan Runner

Division of Reproductive, Abdominal and Radiological Devices
Office of Device Evaluation, Center for Devices and Radiological Health

K062789

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

November 21, 2006

SYNTHES (USA)
1230 WILSON DRIVE
WEST CHESTER, PA 19380
ATTN: JEFFREY DOW

510(k) Number: K062789
Product: SYNTHES (USA)
RAPID RESORBABLE
FIXATION SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

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If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

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

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

September 25, 2006

SYNTHES (USA)
1230 WILSON DRIVE
WEST CHESTER, PA 19380
ATTN: JEFFREY DOW

510(k) Number: K062789
Received: 22-SEP-2006
Product: SYNTHES (USA) RAPID RESORBABLE FIXATION SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRHs e-Copy Program, you may replace one paper copy of an premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

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Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

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

September 19, 2006

SYNTHES (USA)
1230 WILSON DRIVE
WEST CHESTER, PA 19380
ATTN: JEFFREY DOW

510(k) Number: K062789
Received: 18-SEP-2006
Product: SYNTHES (USA) RAPID
User Fee ID Number: 6027028IXATION
SYSTEM

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier(e.g.,Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at 301-827-2860. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

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

1C062789

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

SYNTHES USA INC
1230 Wilson Drive
West Chester PA 19380
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)

2. CONTACT NAME
KATHY ANDERSON

2.1 E-MAIL ADDRESS
andersonk@synthes.com

2.2 TELEPHONE NUMBER (include Area code)
484-356-9733

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
484-356-9682

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/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)
[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4)
10-Aug-2006

Form FDA 3601 (08/2003)

Close Window

1C 15

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SYNTHES®

Synthes (USA)
1302 Wrights Lane East
West Chester, PA 19380

September 12, 2006

510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Synthes (USA) Rapid Resorbable Line Extension – Expanded Indications for Use

Dear Sir/Madam:

These documents constitute a Premarket Notification [510(k) Notification] relating to the intention of Synthes (USA) [Synthes] to market components previously cleared under the Synthes (USA) Poly (L-Lactide-co-Glycolide) Resorbable System (K030069) and Rapid Resorbable Tack System (K050204) with an expanded indication for use to include the pediatric population.

It is our opinion that our product is substantially equivalent to another commercially available product described herein, and that the attached documents support this opinion.

If you have any questions concerning this submission, please do not hesitate to contact me at (484) 356-9720. Thank you for your consideration.

Sincerely,

Jeffrey Dow
Director of RA/CA, Biomaterials
Synthes (USA)

/enc.

"SYNTHES" and ASIF are registered trademarks of Synthes (USA) and Synthes AG Chur.

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SYNTHES®

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

Synthes (USA) Premarket Notification [510(k)]
Synthes (USA) Rapid Resorbable Fixation System – Expanded Indications for Use

Submitted by:
Synthes (USA)
1230 Wilson Drive
West Chester, PA 19380
(484) 356-9720
Fax (484) 356-9682

Contact Name:
Jeffrey Dow
Jeffrey.dow@synthes.com

SYNTHES®

Table of Contents

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SYNTHES®

1.0 Truth and Accuracy Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT*

[As Required By 21 CFR 807.87(k)]

I certify that, in my capacity as Director of RA/CA - Biomaterials, of Synthes (USA), 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.

Jeffrey Dow, Director of RA/CA, Biomaterials

September 12, 2006

K _____ Synthes (USA) Rapid Resorbable Fixation System

*Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K062789

Device Name: Synthes (USA) Rapid Resorbable Fixation System

Indications:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

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K062789

3.0 Summary of Safety and Effectiveness Information

SPONSOR:	Synthes (USA) 1302 Wrights Lane East West Chester, PA 19308 (610) 719-5000
DEVICE NAME:	Synthes (USA) Rapid Resorbable Fixation System
CLASSIFICATION:	Class II, §872.4760 - Bone Plate Class II, §888.3030 – Screw Fixation, Intraosseous Class II, §882.5360 – Cranioplasty plate fastener
PREDICATE DEVICE:	Synthes (USA) Rapid Resorbable Tack System Synthes (USA) Poly (L-Lactide-co-Glycolide) Resorbable Fixation System Synthes (USA) Rapid Resorbable Cranial Clamp Biomet, Inc., Lactosorb Trauma Plating System
DEVICE DESCRIPTION:	The Synthes Rapid Resorbable Fixation System consists of Plates, Meshes, Sheets, Screws and Tacks. The system is provided in a variety of shapes and sizes and, when used in conjunction with resorbable screws, the system provides fixation and aids in the alignment and stabilization of craniofacial bones. To facilitate shaping to the contours of the anatomy, the thermoplastic implants may be heated above the glass transition temperature of 55°C or they may be cut to the desired shape.
INTENDED USE:	The Synthes (USA) Rapid Resorbable Fixation System is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations. In addition, resorbable meshes, sheets, screws and tacks may be used in non-load bearing applications for maintaining the relative position of, and /or containing, bony fragments, bone grafts, (autograft or allograft), or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.
CONTRAINDICATIONS:	These devices are not intended for use in load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. The Synthes Rapid Resorbable System is not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.
SUBSTANTIAL EQUIVALENCE	Comparative information presented supports substantial equivalence.
MATERIAL:	Poly (L-lactide-co-glycolide)

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4.0 Device Name

Synthes (USA) [Synthes] Rapid Resorbable Fixation System

5.0 Establishment Registration

Synthes is registered with the Device Registration and Listing Branch of the Food and Drug Administration (FDA). The device system is manufactured by Synthes GmbH, Oberdorf, Switzerland CH-4336 (FDA Registration #8030965).

6.0 Classification Information

The classification of the Synthes Rapid Resorbable System retains the classification as previously cleared (K030069/K050204), which has been determined to be Class II, as per Title 21 of the Code of Federal Regulations, sections §872.4760 - Bone Plate, §888.3030 – Screw Fixation, Intraosseous, §882.5360 – Cranioplasty plate fastener.

7.0 Information Relating to Performance Standards and Special Controls

The material used in the manufacture of the Synthes Rapid Resorbable System is 85:15 Poly (L-lactide-co-gylcolide). There are no changes in the material from that which was cleared in K030069 Synthes Poly (L-Lactide-co-Glycolide) Resorbable System and K050204 Synthes Rapid Resorbable Tack System. This is also the same material used in K041611 Synthes Rapid Resorbable Cranial Clamp, which has been cleared for adult and pediatric populations. Synthes is not aware of any performance standards or special controls established to date.

8.0 Sterilization Information

Synthes will provide the device sterile through gamma radiation sterilization. There is no change in sterilization information from that submitted in K030069 and K050204. The sterilization process for the Rapid Resorbable System is determined to assure a sterility assurance level (SAL) of 10^{-6} in accordance with ANSI/AAMI/ISO 11137, *Sterilization of healthcare products – Requirements for validation and routine control – Radiation Sterilization.* This device is intended for single use only.

9.0 Description of the Device

The Synthes Rapid Resorbable Fixation System consists of Plates, Meshes, Sheets, Screws and Tacks. The system is provided in a variety of shapes and sizes and, when used in conjunction with resorbable screws, the system provides fixation and aids in the alignment and stabilization of craniofacial bones.

To facilitate shaping to the contours of the anatomy, the thermoplastic implants may be heated above the glass transition temperature of 55°C or they may be cut to the desired shape.

Because the polymer is radiolucent, the implants will not interfere with radiographic evaluation nor will they be affected by radiation therapy. The substantial amorphous structure of the material degrades without inflammatory complications or foreign body responses.

The material resorbs in approximately 12 months.

The Rapid Resorbable System will be used in adult and pediatric clinical procedures including but not limited to:

Trauma of the mid-face or craniofacial skeleton

- Comminuted fractures of the naso-ethmoidal infraorbital areas
- Comminuted fractures of the frontal sinus wall
- Midface or craniofacial trauma
- LeFort (I,II,III) fractures
- Orbital floor fractures
- Fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones
- Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones.

Reconstructive procedures of the midface or craniofacial skeleton

- Craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma,etc.)
- LeFort (I,II,III) osteotomies
- Tumor reconstruction in midface, craniofacial or cranial procedures
- Bone graft procedures in the midface or craniofacial skeleton including: frontal, parietal, temporal, sphenoid, alveolar, and occipital bones
- Craniotomy flap fixation
- Reconstruction of the cranial skull base including sellar floor reconstruction.

There have been minor design changes and additions to the Synthes Rapid Resorbable System since the original submission. Utilizing the CDRH Guidance for *When to File a 510(k)*, Synthes determined that no new 510(k) was required for the following design changes or additions.

In 2003, several design changes were incorporated to the plates. Refer to engineering rationale dated August 29, 2006, **Attachment 4(a)**. A document to file was determined to be adequate based on the following:

- Identical indications as the predicate device
- No material changes
- No impact on plate strength.
- Engineering rationale supports no new issues of safety and effectiveness due to the design changes.

In August 2003, Synthes evaluated proposed changes to the burr hole cover design which included adding additional holes around the perimeter of the implant. The holes give the surgeons the option of securing the burr hole cover with screws or tacks. In order to make the disk more flexible, fingers in a pinwheel fashion were incorporated. See engineering rationale

dated August 13, 2003 in **Attachment 4(b).** A document to file was determined to be adequate based on the following:

- Identical indications as the predicate device
- No material changes
- Same outside diameter and thickness
- Equivalent volume to other implants
- Engineering rationale supports no new issues of safety and effectiveness due to the design change of the burr hole covers.

In April 2004, Synthes evaluated proposed additional Rapid Resorbable Strut Plates. See engineering rationale (Regulatory Pathway Form) dated April 9. 2004, **Attachment 4(c)**. A document to file was determined to be adequate based on the following:

- Identical indications as the predicate device
- No material changes
- Dimensionally equivalent
- Engineering rationale supports no new issues of safety and effectiveness due to the addition of the proposed strut plates.

In January 2006, Synthes evaluated proposed additional Rapid Resorbable Plates in various shapes. See engineering rationales dated February 2 and 6, 2006, **Attachment 4(d).** A document to file was determined to be adequate based on the following:

- Identical indications as the predicate device
- No material changes
- Equivalent volume and material thickness
- Equivalent screw hole diameter and thickness
- Engineering rationale supports no new issues of safety and effectiveness due to the addition of the proposed plates.

Therefore, the Rapid Resorbable System, which is the subject of this 510(k) submission, incorporates the additional design changes, which were implemented as Documents to File, along with the expanded indication statement.

A list of system components can be found in **Attachment 2,** which are the same as those cleared in K050204 and K030069, with the additional components implemented as Documents to File annotated in bold.

10.0 Proposed Labels/Labeling

Please see **Attachment 2**.

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11.0 Commercially Available Device Information

The predicate devices, Synthes Poly (L-Lactide-co-Glycolide) Resorbable System (K030069); Synthes Rapid Resorbable Tack System (K050204); Synthes (USA) Rapid Resorbable Cranial Clamp (K041611); Biomet, Inc., Lactosorb Trauma Plating System (K971870); have been cleared for commercial distribution via the pre-market notification process. Information on these devices can be found in **Attachment 3.**

12.0 Comparison to Commercially Available Device(s)

A comparison of the Synthes Rapid Resorbable Fixation System to the predicate devices follows on the next page:

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New Device Synthes Rapid Resorbable Fixation System (expanded indications) (Ref: K030069/K050204)	Predicate Device Synthes Rapid Resorbable Cranial Clamp, (K041611)	Predicate Device Biomet, Inc. LactoSorb Trauma Plating System (K971870)
Proposed Indications: Intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in **pediatric and** adult populations. In addition, resorbable meshes, sheets, screws and tacks may be used in non-load bearing applications for maintaining the relative position of, and /or containing, bony fragments, bone grafts, (autograft or allograft), or bone graft substitutes in reconstruction of the craniofacial or mandibular areas. **Current Indications:** **K030069 Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System** Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System devices (Plates, Meshes, Sheets and Screws) are intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Resorbable Meshes, Sheets and Screws may be used in non-load bearing applications for maintaining the relative position of and / or containing bony fragments, bone grafts (autograft or allograft)j or bone graft substitutes in reconstruction of the craniofacial or mandibular areas. **K050204 Synthes Rapid Resorbable Tack System** Synthes Rapid Resorbable Tack System is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Rapid Resorbable Tacks may be used in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.	**Indications:** Intended for covering burr holes and for fixation of cranial bone flaps, in **pediatric and adult patients.**	**Indications:** The LactoSorb Trauma Plating System is indicated for use in the following midface or craniofacial procedures. **General Indication:** trauma procedures of the midface or craniofacial skeleton. **Specific Indications:** Comminuted fractures of the naso-ethmoidal infraorbital areas; comminuted fractures of the frontal sinus wall; **pediatric midface or craniofacial trauma**; LeFort (I, II, III) fractures; orbital floor fractures; fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones; trauma of the craniofacial skeleton including frontal, parietal, temporal, sphenoid and occipital bones. **General Indications:** reconstructive procedures of the midface or craniofacial skeleton. **Specific Indications:** Infant craniofacial surgery; LeFort (I, II, III) osteotomies; tumor reconstruction in midface or craniofacial procedures; bone graft procedures in the midface or craniofacial skeleton; **pediatric reconstructive procedures**; reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones; craniotomy flap fixation. This system is not designed for use in the mandible and/or full load bearing procedures.

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New Device **Synthes** **Rapid Resorbable Fixation System** **(expanded indications)** **(Ref: K030069/K050204)**	**Predicate Device** **Synthes** **Rapid Resorbable Cranial Clamp,** **(K041611)**	**Predicate Device** **Biomet, Inc.** **LactoSorb Trauma Plating System** **(K971870)**
Features: - Resorbable copolymer material - Radiolucent polymer does not interfere with intra- or postoperative radiographs - Polymer strength is not affected by radiation therapy - Eliminates secondary surgeries for implant removal	**Features:** - Resorbable copolymer material - Flexible concave disks for improved fixation due to compression - Ratcheting center shaft that adjusts to various bone flap thicknesses - Low profile design to minimize irritation	**Features:** - Resorbable copolymer material - Device completely resorbs by 12 months in vivo eliminating the need for long-term removal
Design: A wide assortment of implants (i.e. plates, meshes, sheets, screws, and tacks) are available in the Synthes Rapid Resorbable Fixation System. Design includes beveled edge for reduced palpability, optimized screw recess for low profile.	**Design:** Clamp design consisting of two disks connected by a ratcheting center shaft that locks.	**Design:** Plates, mesh and screws
Dimensions: *Screws* - Lengths: 3mm to 8 mm Diameter: 1.5mm, 2.0mm and 2.5mm *Plates , Meshes and Sheets* – Thickness: 0.25 mm, 0.5mm, 0.8mm, and 1.2mm *Tacks* - Overall diameter: 1.6 and 1.75 mm Head diameter: 2.38 mm Rib Pitch: 0.5 – 0.7 Overall lengths: 4 – 6 mm	**Dimensions:** *Disks* – Thickness: 2.0 / 2.2 mm Diameter: 18.0 mm *Shaft* – Width: 4.25 mm (teeth) Thickness: 1.5 mm Length: Adjustable up to 15 mm (max) Overall shaft length: 50 mm	**Dimensions:** Implants are available in a variety of shapes and sizes. **Screws:** 1.5mm: 3 – 8mm lengths 2.0mm: 5 – 17mm odd lengths 2.5mm: 5 – 17mm odd lengths 2.8mm: 11 – 17mm odd lengths.
Material: Poly (L-lactide-co-glycolide), 85:15	**Material:** Poly (L-lactide-co-glycolide), 85:15	**Material:** Poly (L-lactide-co-glycolide), 82:18
Biocompatibility Established	**Biocompatibility** Established	**Biocompatibility** Established
Sterilization: Gamma	**Sterilization:** Gamma	**Sterilization:** Ethylene oxide

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13.0 Determination of Substantial Equivalence: [ref. Office of Device Evaluation (ODE) Blue Book Memorandum #86-3, Attachment I "510(k) "Substantial Equivalence" Decision-Making Process (Detailed)"]

New Device [Synthes Rapid Resorbable Fixation System – Expanded Indications] **is Compared to Marketed Devices** [Synthes (USA) Rapid Resorbable Tack System (K050204); Synthes (USA) Poly (L-Lactide-co-Glycolide) Resorbable Fixation System (K030069); Synthes (USA) Rapid Resorbable Cranial Clamp (K041611); and Biomet, Inc., Lactosorb Trauma Plating System (K971870)].

Does New Device Have Same Indication Statements? Yes, the new device has the same indications as the combined predicate devices. Pediatric indications are being added to the Rapid Resorbable Fixation System. This same material has been cleared for pediatric indications in K041611 Synthes Rapid Resorbable Cranial Clamp. An equivalent system, Biomet, Inc., Lactosorb Trauma Plating System, has also been cleared for adult and pediatric use.

New Device Has Same Intended Use and May be "Substantially Equivalent".

Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.? : Yes. The Rapid Resorbable Fixation System is the same design and material cleared in the Synthes (USA) Rapid Resorbable Tack System (K050204) and Synthes (USA) Poly (L-Lactide-co-Glycolide) Resorbable Fixation System (K030069).

Could the New Characteristics Affect Safety or Effectiveness?

No. The expanded indications for pediatric do not affect safety or effectiveness. The material has been previously cleared for pediatric use (Synthes (USA) Rapid Resorbable Cranial Clamp (K041611)). Biocompatibility has already been established.

A similar system, Biomet, Inc., Lactosorb Trauma Plating System is currently used for pediatric populations in trauma and reconstructive procedures of the midface and craniofacial skeleton for the pediatric population.

Various published journal articles support the use of resorbable implant for craniofacial reconstruction in the pediatric population. Refer to Summary of Articles, **Attachment 5.**

Substantial Equivalence Determination

14.0 Confidentiality Certification

We consider our intent to market this device to be confidential commercial information. Synthes has not disclosed the intent to market this product to others who are not collaborators and consultants. We have taken caution to protect the confidentiality of our intent.

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15.0 Attachments

Attachment 1:	List of Components
Attachment 2:	Proposed Labels/Labeling
Attachment 3:	Commercially Available Device Information
Attachment 4:	Engineering Rationales
Attachment 5:	Journal Articles

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Attachment 1:

List of Components

Reference K030069 - Rapid Resorbable Fixation System			
Original Part Number	**Part Number Change Only**	**Sterile P/N** (additional package sizes may be available .XXS)	**Description** (bolded items = document to file)
			2.0 mm Plates
M01029-2002	852.002	852.002.01S	Straight Plate, 2 holes
M01029-2004	852.004	852.004.01S	Straight Plate, 4 holes
M01029-2008	852.008	852.008.01S	Adaption Plate, 8 holes
M01029-2012	852.012	852.012.01S	Adaption Plate, 12 holes
M01029-2020	852.020	852.020.01S	Adaption Plate, 20 holes
M01029-2110	852.110	852.110.01S	Orbital Rim, 10 holes
M01029-2263	852.263	852.263.01S	Oblique L-Plate, 6x4 holes, left
M01029-2264	852.264	852.264.01S	Oblique L-Plate, 6x4 holes, right
(1/2006)	**852.265**	**852.265.01S**	**90 Degree L-Plate, 2x2 holes, left**
(1/2006)	**852.266**	**852.265.01S**	**90 Degree L-Plate, 2x2 holes, right**
M01029-2343	852.343	852.343.01S	Y-Plate, 4x3x3 holes
M01029-2420	852.420	852.420.01S	Strut Plate, 2 x 10 holes
M01029-2421	852.421	852.421.01S	Strut Plate, 2 x 18 holes
M01029-2422	852.422	852.422.01S	Strut Plate, 2 x 36 holes
M01029-2423	852.423	852.423.01S	Strut Plate, 3 x 36 holes

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			2.0 mm Meshes
M01029-2520	852.520	852.520.01S	Mesh, 48x48x1.2 mm
M01029-2521	852.521	852.521.01S	Mesh, 78x78x1.2 mm
M01029-2522	852.522	852.522.01S	Mesh, 102x102x1.2 mm
M01029-2523	852.523	852.523.01S	Mesh, 126x126x1.2 mm
M01029-4001	852.610	852.610.01S	Contourable mesh, square, 20x20x1.2 mm
M01029-4002	852.611	852.611.01S	Contourable mesh, square, 50x50x1.2 mm
M01029-4003	852.612	852.612.01S	Contourable mesh, square, 100x100x1.2 mm
M01029-4004	852.613	852.613.01S	Contourable mesh, square, 150x150x1.2 mm
M01029-4101	852.640	852.640.01S	Contourable mesh, round, ∅20mm, 1.2 mm
M01029-4102	852.641	852.641.01S	Contourable mesh, round, ∅50mm, 1.2 mm
M01029-4103	852.642	852.642.01S	Contourable mesh, round, ∅100mm, 1.2 mm
M01029-4104	852.643	852.643.01S	Contourable mesh, round, ∅150mm, 1.2 mm
M01029-4201	852.670	852.670.01S	Contourable mesh, crescent, 49.5mm, 1.2 mm
M01029-4202	852.671	852.671.01S	Contourable mesh, crescent, 77mm, 1.2 mm
M01029-6001	852.700	852.700.01S	Straight row mesh, square, 18x18x1.2 mm
M01029-6002	852.720	852.720.01S	Straight row mesh, square, 48x48x1.2 mm
M01029-6003	852.722	852.722.01S	Straight row mesh, square, 102x102x1.2 mm
M01029-6004	852.723	852.723.01S	Straight row mesh, square, 150x150x1.2 mm
			2.0 mm Screws
M01029-0011	806.004	806.004.02S	Cortex Screw, 2.0x4 mm
M01029-0012	806.005	806.005.02S	Cortex Screw, 2.0x5 mm
M01029-0013	806.006	806.006.02S	Cortex Screw, 2.0x6 mm
M01029-0014	806.007	806.007.02S	Cortex Screw, 2.0x7 mm
M01029-0015	806.008	806.008.02S	Cortex Screw, 2.0x8 mm
M01029-0021	806.044	806.044.02S	Cortex Screw, emergency, 2.5x 4 mm
M01029-0022	806.045	806.045.02S	Cortex Screw, emergency, 2.5x 5 mm
M01029-0023	806.046	806.046.02S	Cortex Screw, emergency, 2.5x 6 mm
M01029-0024	806.047	806.047.02S	Cortex Screw, emergency, 2.5x 7 mm
M01029-0025	806.048	806.048.02S	Cortex Screw, emergency, 2.5x 8 mm
			1.5 mm Plates
M01029-1002	851.002	851.002.01S	Straight Plate, 2 holes
M01029-1004	851.004	851.004.01S	Straight Plate, 4 holes
M01029-1008	851.008	851.008.01S	Adaption Plate, 8 holes

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			1.5 mm Plates (continued)
(1/2006)	**851.009**	**851.009.01S**	**Adaption Plate, Scalloped, 8 holes**
M01029-1012	851.012	851.012.01S	Adaption Plate, 12 holes
M01029-1020	851.020	851.020.01S	Adaption Plate, 20 holes
(1/2006)	**851.021**	**851.021S**	**Adaption Plate, Scalloped, 20 holes**
M01029-1110	851.110	851.110.01S	Orbital Rim, 10 holes
M01029-1263	851.263	851.263.01S	Oblique L-Plate, 6x4 holes, left
M01029-1264	851.264	851.264.01S	Oblique L-Plate, 6x4 holes, right
M01029-1320	851.320	851.320.01S	Double Y-Plate, 10 holes
M01029-1343	851.343	851.343.01S	Y-Plate, 4x3x3 holes
(1/2006)	**851.344**	**851.343.0S**	**T-Plate, 3x3 hole**
M01029-1420	851.420	851.420.01S	Strut Plate, 2 x 10 holes
M01029-1421	851.421	851.421.01S	Strut Plate, 2 x 18 holes
M01029-1422	851.422	851.422.01S	Strut Plate, 2 x 36 holes
M01029-1423	851.423	851.423.01S	Strut Plate, 3 x 36 holes
(4/2004)	**851.424**	**851.424.01S**	**Strut Plate, scalloped, 2 x 20 holes**
(4/2004)	**851.425**	**851.425.01S**	**Strut Plate, scalloped, 2 x 18 hole**
(4/2004)	**851.426**	**851.426.01S**	**Strut Plate, scalloped, 2 x 36 hole**
(1/2006)	**851.436**	**851.436.01S**	**Strut Plate, scalloped, 2 x 36 hole (1.2 thk)**
(1/2006)	**851.500**	**851.500.01S**	**Box Plate, 4 hole**
M01029-1506	851.506	851.506.01S	Burr hole cover
M01029-1507	851.507	851.507.01S	Burr hole cover, small
M01029-1508	851.508	851.508.01S	Burr hole cover disk
M01029-1540	851.540	851.540.01S	Orbital Floor Plate, 24 x 24 mm
M01029-1541	851.541	851.541.01S	Orbital Floor Plate, Medium, 30x30 mm
M01029-1542	851.542	851.542.01S	Orbital Floor Plate, Large, 35x35 mm
(1/2006)	**851.689**	**851.689.01S**	**Orbital Floor Plate w/Bending Template, 24 mm**
(1/2006)	**851.690**	**851.690.01S**	**Orbital Floor Plate w/Bending Template, 30 mm**
(1/2006)	**851.691**	**851.691.01S**	**Orbital Floor Plate w/Bending Template, 35 mm**
M01029-1604	851.604	851.604.01S	X-Plate, 4 holes
(1/2006)	**851.605**	**851.605.01S**	**X-Plate, 8 hole**
			1.5 mm Meshes
M01029-1510	851.510	851.510.01S	Mesh, 50x50x0.5 mm
M01029-151	851.511	851.511.01S	Mesh, 60x80x0.5 mm

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			1.5 mm Meshes (continued)
M01029-1512	851.512	851.512.01S	Mesh, 100x100x0.5mm
M01029-1520	851.520	851.520.01S	Mesh, 50x50x0.8 mm
M01029-1521	851.521	851.521.01S	Mesh, 100x100x0.8 mm
M01029-1522	851.522	851.522.01S	Mesh, 125x125x0.8 mm
M01029-1523	851.523	851.523.01S	Mesh, 75x75x0.8 mm
M01029-3001	851.610	851.610.01S	Contourable mesh, square, 20x20x0.25 mm
M01029-3002	851.611	851.611.01S	Contourable mesh, square, 50x50x0.25 mm
M01029-3003	851.612	851.612.01S	Contourable mesh, square, 100x100x0.25 mm
M01029-3004	851.613	851.613.01S	Contourable mesh, square, 150x150x.025 mm
M01029-3005	851.620	851.620.01S	Contourable mesh, square, 20x20x0.5 mm
M01029-3006	851.621	851.621.01S	Contourable mesh, square, 50x50x0.5 mm
M01029-3007	851.622	851.622.01S	Contourable mesh, square, 100x100x0.5 mm
M01029-3008	851.623	851.623.01S	Contourable mesh, square, 150x150x0.5 mm
M01029-3009	851.630	851.630.01S	Contourable mesh, square, 20x20x0.8 mm
M01029-3010	851.631	851.631.01S	Contourable mesh, square, 50x50x0.8 mm
M01029-3011	851.632	851.632.01S	Contourable mesh, square, 100x100x0.8 mm
M01029-3012	851.633	851.633.01S	Contourable mesh, square, 150x150x0.8 mm
M01029-3101	851.640	851.640.01S	Contourable mesh, round, ∅20mm, 0.25 mm
M01029-3102	851.641	851.641.01S	Contourable mesh, round, ∅50mm, 0.25 mm
M01029-3103	851.642	851.642.01S	Contourable mesh, round, ∅100mm, 0.25 mm
M01029-3104	851.643	851.643.01S	Contourable mesh, round, ∅150mm, 0.25 mm
M01029-3105	851.650	851.650.01S	Contourable mesh, round, ∅20mm, 0.5 mm
M01029-3106	851.651	851.651.01S	Contourable mesh, round, ∅50mm, 0.5 mm
M01029-3107	851.652	851.652.01S	Contourable mesh, round, ∅100mm, 0.5 mm
M01029-3108	851.653	851.653.01S	Contourable mesh, round, ∅150mm, 0.5 mm
M01029-3109	851.660	851.660.01S	Contourable mesh, round, ∅20mm, 0.8 mm
M01029-3110	851.661	851.661.01S	Contourable mesh, round, ∅50mm, 0.8 mm
M01029-3111	861.662	861.662.01S	Contourable mesh, round, ∅100mm, 0.8 mm
M01029-3112	851.663	851.663.01S	Contourable mesh, round, ∅150mm, 0.8 mm
M01029-3201	851.670	851.670.01S	Contourable mesh, crescent, 45mm, 0.25 mm
M01029-3202	851.671	851.671.01S	Contourable mesh, crescent, 75mm, 0.25 mm
M01029-3203	851.672	851.672.01S	Contourable mesh, crescent, 45mm, 0.5 mm

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			1.5 mm Meshes (continued)
M01029-3204	851.673	851.673.01S	Contourable mesh, crescent, 75mm, 0.5 mm
M01029-3205	851.674	851.674.01S	Contourable mesh, crescent, 45mm, 0.8 mm
M01029-3206	851.675	851.675.01S	Contourable mesh, crescent, 75mm, 0.8 mm
M01029-5001	851.700	851.700.01S	Straight row mesh, square, 20x120x0.25 mm
M01029-5002	851.701	851.701.01S	Straight row mesh, square, 50x50x0.25 mm
M01029-5003	851.702	851.702.01S	Straight row mesh, square, 100x100x0.25 mm
M01029-5004	851.703	851.703.01S	Straight row mesh, square, 150x150x0.25 mm
M01029-5005	851.710	851.710.01S	Straight row mesh, square, 20x120x0.5 mm
M01029-5006	851.711	851.711.01S	Straight row mesh, square, 50x50x0.5 mm
M01029-5007	851.712	851.712.01S	Straight row mesh, square, 100x100x0.5 mm
M01029-5008	851.713	851.713.01S	Straight row mesh, square, 150x150x0.5 mm
M01029-5009	851.720	851.720.01S	Straight row mesh, square, 20x120x0.8 mm
M01029-5010	851.721	851.721.01S	Straight row mesh, square, 50x50x0.8 mm
M01029-5011	851.722	851.722.01S	Straight row mesh, square, 100x100x0.8 mm
M01029-5012	851.723	851.723.01S	Straight row mesh, square, 150x150x0.8 mm
(1/2006)	**851.724**	**851.724.01S**	**Straight row mesh, square,75x75x0.8 mm**
			1.5 mm Sheets
M01029-1532	851.532	851.532.01S	Sheet, square, 50x50x0.5 mm
M01029-1533	851.533	851.533.01S	Sheet, square, 75x75x0.5 mm
M01029-1534	851.534	851.534.01S	Sheet, square, 50x50x0.8 mm
M01029-1535	851.535	851.535.01S	Sheet, square, 75x75x0.8 mm
			1.5 mm Screws
M01029-0001	805.603	805.603.02S	Cortex Screw, 1.5x3 mm
M01029-0002	805.604	805.604.02S	Cortex Screw, 1.5x4 mm
M01029-0003	805.605	805.605.02S	Cortex Screw, 1.5x5 mm
M01029-0004	805.606	805.606.02S	Cortex Screw, 1.5x6 mm
M01029-0005	805.607	805.607.02S	Cortex Screw, 1.5x7 mm
M01029-0006	805.608	805.608.02S	Cortex Screw, 1.5x8 mm

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SYNTHES®

Reference K050204 - Rapid Resorbable Tack System		
Part Number Change Only	**Sterile P/N (additional package sizes may be available .XXS)**	**Description**
805.614	805.614.02S	1.5 x 4 mm Resorbable Tack
805.615	805.615.02S	1.5 x 5 mm Resorbable Tack
805.616	805.616.02S	1.5 x 6 mm Resorbable Tack
805.624	805.624.02S	1.7 x 4 mm Resorbable Emergency Tack
805.625	805.625.02S	1.7 x 5 mm Resorbable Emergency Tack
805.626	805.626.02S	1.7 x 6 mm Resorbable Emergency Tack

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Attachment 2:

Proposed Labels/Labeling

a. **Proposed Device Label – Sterile Device**
b. **Proposed Device Specific Insert**

SYNTHES®

a. Proposed Device Label – Sterile Device

(1) Labeling for pouches

Preprinted information:

SYNTHES
1101 Synthes Ave.
Monument, CO 80132

Contents Sterile Unless Package is Opened or Damaged

Caution: Federal law restricts this device to sale by or on the order of a physician

Applied product specific label:

CAT: xxx.xxx
LOT: xxxxxxx
MAT: Material
STERILE
EXPIRATION DATE: xx/xx/xx
Device description
Made in Country

(2) Labeling on outer carton:

Company logo, Synthes
1101 Synthes Ave.
Monument, CO. 80132

Manufacturer of original AO/ASIF Implants
Caution: Federal law restricts this device to sale or on the order of a physician
Contents sterile unless inner package is opened or damaged
IMPORTANT: Read accompanying package insert.

Applied product specific label to carton:

CAT: xxx.xxx
LOT: xxxxxxx
QTY: x
MAT: Material
STERILE
EXPIRATION DATE: xx/xx/xx
Device description
Made in Country

(3) Customer information insert(s) will be placed into the carton:

See insert information provided in "(b) Device Specific Insert".

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SYNTHES®

b. Device Specific Insert

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IMPORTANT INFORMATION

ON THE SYNTHES

RAPID RESORBABLE FIXATION SYSTEM

SYNTHES®
CMF

7/06 GP2332-C

DESCRIPTION

The Synthes Rapid Resorbable Fixation System is comprised of plates, meshes, sheets, screws, and tacks. These implants are made from the resorbable copolymer poly (L-lactide-co-glycolide), which resorbs in vivo by hydrolysis into lactic and glycolic acids, which are then metabolized by the body. Synthes Rapid Resorbable implants are resorbed completely within approximately 12 months. The implants are provided sterile and are intended for single patient use.

INDICATIONS

The Synthes Rapid Resorbable Fixation System devices (plates, meshes, sheets, screws, and tacks) are intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations. In addition, Rapid Resorbable meshes, sheets, screws, and tacks may be used in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

CONTRAINDICATIONS

These devices are not intended for use in full load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Synthes Rapid Resorbable System devices are not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

WARNINGS AND PRECAUTIONS

Synthes Rapid Resorbable plates, meshes, sheets, screws, and tacks are not intended for use in the mandible or other load bearing applications unless used in conjunction with traditional rigid fixation. These devices cannot be expected to replace normal healthy bone or withstand stress placed upon them in full load bearing applications. The devices can break or bend as a result of stress, activity, or full load bearing, which could cause failure of the device or treatment.

The surgeon should be thoroughly familiar with the devices, the method of application, the instruments, and the surgical procedure. The surgeon must select a type or types of internal fixation appropriate for the treatment.

1. Improper selection, placement, positioning, and fixation of the devices can cause subsequent undesirable results.
2. Resorbable devices provide fixation and are NOT intended to replace normal healthy bone or withstand stress of full load bearing.
3. The screws and tacks are NOT to be heated by any means for contouring.
4. Plates and meshes can break or be damaged due to excessive activity or trauma. This could lead to failure of the implant construct, which could require additional surgery and device removal.
5. Discard and DO NOT USE previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged packages.
6. DO NOT USE if there is a loss of sterility of the device.
7. **Store in a dry condition. DO NOT STORE ABOVE 49°C or 120°F.**

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 fixation devices can occur as a result of excessive activity, trauma, or load-bearing.
4. While rare, implantation of foreign materials can result in an inflammatory response or allergic reaction.

STERILIZATION

Implants:
Synthes Rapid Resorbable System implants are sterilized by gamma radiation. DO NOT RESTERILIZE. CONTENTS STERILE UNLESS INSIDE PACKAGE IS OPENED OR DAMAGED.

Instruments:
Most instruments for use with the Synthes Rapid Resorbable System are provided NONSTERILE, unless noted otherwise. The following parameters are for sterilization of the nonsterile instruments:

Method	Cycle	Temperature	Exposure Time
Steam	Gravity Displacement (Wrapped)	132°-135°C (270°-275°F)	15 Minutes
Steam	Pre-vacuum (Wrapped)	132°-135°C (270°-275°F)	8 Minutes

These parameters were validated to sterilize Synthes Rapid Resorbable Fixation System components on their own. If these devices are sterilized using a filtered sterilization container system, the recommended parameters may not be valid and new cycle parameters may have to be established by the user. The user is responsible for validating the process when sterilization container systems are used.

The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION:
FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

SYNTHES®

Attachment 3:

Commercially Available Device Information

510(k) Premarket Notification Database

Device Classification Name	Plate, Bone
510(K) Number	K030069
Regulation Number	872.4760
Device Name	SYNTHES POLY (L-LACTIDE-CO-GLYCOLIDE) RESORBABLE
Applicant	SYNTHES (USA) 1690 Russell Rd. Post Office Box 1766 Paoli, PA 19301
Contact	Bonnie J Smith
Classification Product Code	JEY
Date Received	01/08/2003
Decision Date	04/08/2003
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 7/05/2006

K030069

APR 0 8 2003

2. 510(k) Summary

Submitter: Synthes (USA) 1690 Russell Road, Paoli, PA 19301

Company Contact: Bonnie J. Smith
(610) 647-9700

Name of Device: Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System

Device Classification / Common Name: Class II, 21 CFR §872.4760 – Bone Plate
Class II, 21 CFR §888.3030 – Screw Fixation, Intraosseous

Predicate Device: Lorenz LactoSorb® Trauma Plating System (Biomet) and Synthes Resorbable Fixation System, Poly (L/DL-lactide)

Intended Use: Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System devices (Plates, Meshes, Sheets and Screws) are intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Resorbable Meshes, Sheets and Screws may be used in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

Contraindications: These devices are not intended for use in full load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System devices are not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

Device Description: Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System consists of Plates, Meshes, Sheets and Screws. The system is provided in a variety of shapes and sizes and, when used in conjunction with resorbable screws, the system provides fixation and aids in the alignment and stabilization of craniofacial bones. To facilitate shaping to the contours of the anatomy, the thermoplastic implants may be heated above the glass transition temperature of 55° C or they may be cut to the desired shape.

Material: Poly (L-lactide-co-glycolide)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 8 2003

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K030069
Trade/Device Name: Sythes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: January 6, 2003
Received: January 8, 2003

Dear Ms. Smith:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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2. Indications for Use Statement

510(k) Number (if known): K030069

DEVICE NAME: Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System

INDICATIONS: Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System devices (Plates, Meshes, Sheets, and Screws) are intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Resorbable Meshes, Sheets and Screws may be used in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

CONTRAINDICATIONS: These devices are not intended for use in full load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System devices are not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

(PLEASE NO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Ken Mudy for MSH
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K030069

Synthes (USA)
Premarket Notification 510(k)
PLLA/PGA Resorbable Fixation System

CONFIDENTIAL

510(k) Premarket Notification Database

Device Classification Name	Plate, Bone
510(K) Number	K050204
Regulation Number	872.4760
Device Name	SYNTHES RAPID RESORBABLE TACK SYSTEM
Applicant	SYNTHES (USA) 1690 Russell Rd. Paoli, PA 19301
Contact	Sheri L Musgnung
Classification Product Code	JEY
Date Received	01/28/2005
Decision Date	03/04/2005
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 7/05/2006

SYNTHES®

MAR 4 - 2005

K050204

3.0 **510(k) Summary**

Sponsor: Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device Name: Synthes Rapid Resorbable Tack System

Classification: Class II, 21 CFR §882.5360
Cranioplasty plate fastener

Predicate Device: Synthes Resorbable Tack System
Synthes Rapid Resorbable Fixation System (aka Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System

Device Description: The Synthes Rapid Resorbable Tack System consists of resorbable tacks and accessory instruments, which are additional components of the Synthes Rapid Resorbable Fixation System. The Rapid Resorbable Tack System consists of 1.5 mm tacks and 1.7 mm emergency tacks and are available in lengths ranging from 4 – 6 mm.

Intended Use: Synthes Rapid Resorbable Tack System is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Rapid Resorbable Tacks may be used in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

Contraindications: These devices are not intended for use in load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Synthes Rapid Resorbable Tacks are not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

Substantial Equivalence: Documentation is provided which demonstrates that Synthes Rapid Resorbable Tack System is substantially equivalent to other legally marketed Synthes devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 - 2005

Ms. Sheri L. Musgnung
Senior Regulatory Affairs Specialist
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K050204
Trade/Device Name: Synthes Rapid Resorbable Tack System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: March 2, 2005
Received: March 3, 2005

Dear Ms. Musgnung:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

Indications for Use

510(k) Number (if known): K050204

Device Name: Synthes Rapid Resorbable Tack System

Indications: Synthes Rapid Resorbable Tack System is intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Rapid Resorbable Tacks may be used in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

Contraindications: These devices are not intended for use in load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Synthes Rapid Resorbable Tacks are not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...tion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices

...(s) Number K050204

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New Search
Back To Search Results

510(k) Premarket Notification Database

Device Classification Name	Cover, Burr Hole
510(K) Number	K041611
Regulation Number	882.5250
Device Name	SYNTHES (USA) RAPID RESORBABLE CRANIAL CLAMP
Applicant	SYNTHES (USA) 1690 Russell Rd. Paoli, PA 19301
Contact	Lisa M Boyle
Classification Product Code	GXR
Subsequent Product Code	HBW
Date Received	06/15/2004
Decision Date	09/08/2004
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Neurology
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 7/05/2006

SYNTHES®

SEP - 8 2004

K041611

3.0 **510(k) Summary**

Sponsor:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device Name:

Class II, §882.5250 – Burr hole cover
Class II, §882.5360 – Cranioplasty plate fastener

Classification:

Title 21 CFR 882.5250: Burr Hole Cover and section 882.5360: Cranioplasty Plate Fastener.

Predicate Device:

Synthes Resorbable Cranial Clamp
Biomet Lactosorb RapidFlap

Device Description:

Synthes Rapid Resorbable Cranial Clamp consists of two disks connected by a tensioned ratcheting shaft. The clamps fit a range of burr holes and craniotomy gap sizes.

Intended Use:

Synthes Rapid Resorbable Cranial Clamp is intended for covering burr holes and for fixation of cranial bone flaps in adult and pediatric populations.

Substantial Equivalence:

Documentation was provided which demonstrated the Synthes Rapid Resorbable Cranial Clamp to be substantially equivalent to other legally marketed devices.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Ms. Lisa M. Boyle
Regulatory Associate
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K041611
Trade/Device Name: Rapid Resorbable Cranial Clamp
Regulation Number: 21 CFR 882.5250, 21 CFR 882.5360
Regulation Name: Burr hole cover, Cranioplasty plate fastener
Regulatory Class: II
Product Code: GXR, HBW
Dated: June 14, 2004
Received: June 15, 2004

Dear Ms. Boyle:

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

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

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

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

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

Sincerely yours,

for Mark N. Melkerson

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

Enclosure

SYNTHES®

2.0 **Indications for Use**

510(k) Number (if known): K041611

Device Name: Rapid Resorbable Cranial Clamp

Indications for Use: Synthes Rapid Resorbable Cranial Clamp is indicated for covering burr holes and for fixation of cranial bone flaps in adult and pediatric populations.

Prescription Use ___ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K041611

510(k) Premarket Notification Database

Device Classification Name	Plate, Fixation, Bone
510(K) Number	K971870
Regulation Number	888.3030
Device Name	LACTOSORB TRAUMA PLATING SYSTEM
Applicant	BIOMET, INC. Airport Industrial Park, P.O.Box 587 Warsaw, IN 46581 0587
Contact	Mary Verstynen
Classification Product Code	HRS
Subsequent Product Code	HWC
Date Received	05/21/1997
Decision Date	08/19/1997
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary/Purged 510(K)
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 7/05/2006

K971870

Summary of Safety and Effectiveness

AUG 19 1997

The LactoSorb® Trauma Plating System is indicated for use in the following midface or craniofacial procedures.

A. General Indication: trauma procedures of the midface or craniofacial skeleton

Specific Indications:

1. comminuted fractures of the naso-ethmoidal infraorbital areas
2. comminuted fractures of the frontal sinus wall
3. pediatric midface or craniofacial trauma
4. LeFort (I,II,III) fractures
5. orbital floor fractures
6. fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones
7. trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones

B. General Indication: reconstructive procedures of the midface or craniofacial skeleton

Specific Indications:

1. Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.)
2. LeFort (I,II,III) osteotomies
3. tumor reconstruction in midface or craniofacial procedures
4. bone graft procedures in the midface or craniofacial skeleton
5. pediatric reconstructive procedures
6. reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
7. craniotomy flap fixation

This system is not designed for use in the mandible and/or full load bearing procedures.

The LactoSorb® plates/mesh/screws are made of bioresorbable and biocompatible polymer that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic (PLA/PGA) acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The safety of PLA/PGA material has been well documented since the early 1970's when the FDA first approved the use of

resorbable PLA/PGA sutures. The exact same LactoSorb® material has been implanted in humans for over 10 years in the Poly Surgiclip® device manufactured by United States Surgical Corporation. The LactoSorb® material has been found to be biocompatible in both soft and hard bone tissue.

The effectiveness of this resorbable system was determined by mechanical testing and an FDA approved clinical study. The LactoSorb® system was found to provide adequate fixation in the craniomaxillofacial region with no device related complications reported. This system is as effective as similar metal micro fixation systems on the market. The devices completely resorbs by 12 months IN VIVO eliminating the need for long-term removal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1997

Ms. Mary L. Verstynen
Clinical Research Manager
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K971870
Trade Name: LactoSorb® Trauma Plating System
Regulatory Class: II
Product Codes: HRS and HWC
Dated: May 20, 1997
Received: May 21, 1997

Dear Ms. Verstynen:

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

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

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) 594-4595. 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,

for 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

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K971870

510(k) Number (if known):_____

Device Name: LactoSorb Trauma Plating System

Indications For Use:

A. General Indication: trauma procedures of the midface or craniofacial skeleton
   Specific Indications:
   1. Comminuted fractures of the naso-ethmoidal infraorbital areas
   2. Comminuted fractures of the frontal sinus wall
   3. Pediatric midface or craniofacial trauma
   4. Lefort (I,II,III) fractures
   5. Orbital floor fractures
   6. Fractures of the maxilla, Zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones
   7. Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones

B. General Indication: reconstructive procedures of the midface or craniofacial skeleton
   Specific Indications:
   1. Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma etc.)
   2. Lefort (I,II,III) osteotomies
   3. Tumor reconstruction in midface or craniofacial procedures
   4. Bone graft procedures in the midface or craniofacial skeleton
   5. Pediatric reconstructive procedures
   6. Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
   7. Craniotomy flap fixation

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971870

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use ___

(Optional Format 1-2-96)

00013

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Attachment 4:

Engineering Rationales

(a) August 29, 2006
(b) August 13, 2003
(c) April 9, 2004
(d) February 2 and 6, 2006

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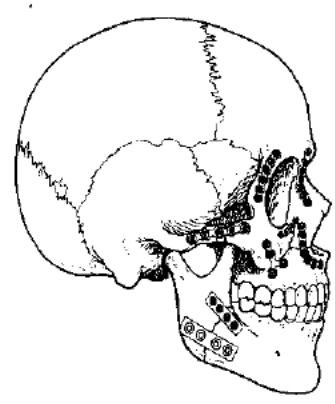
4(a) Engineering rationale dated August 29, 2006

SYNTHES

Polymer Development

29 August 2006



To: DHF M01-029 Rapid Resorbable System

Cc: Regulatory Department

From: Ralph Zwimmann 29AUG06

Re: Modification to Rapid Resorbable Plates

Rationale regarding changes to plates:

- The following changes were incorporated in 2003.
- A bevel was added to the outer edge and a shallow groove to the center of the top surface in order to give the surgeon tactile feedback indicating the top side of the plate. The addition of these features required that the plate become 1mm wider and, thereby, 1mm longer in order to maintain similar strength. The plate thickness remained the same.

Old Part Number	AO Part Number	Description
M01029_1002	851.002	1.5mm Straight Plate, 2 holes
M01029_1004	851.004	1.5mm Straight Plate, 4 holes
M01029_2002	852.002	2.0mm Straight Plate, 2 holes
M01029_2004	852.004	2.0mm Straight Plate, 4 holes

- (b)(4) [redacted]

Old Part Number	AO Part Number	Description
M01029_1110	851.110	1.5mm Orbital Rim Plate, 10 holes

M01029_1263	851.263	1.5mm Oblique L-Plate, 6x4 holes, left
M01029_1264	851.264	1.5mm Oblique L-Plate, 6x4 holes, right
M01029_1420	851.420	1.5mm Strut Plate, 2x10 holes
M01029_1421	851.421	1.5mm Strut Plate, 2x18 holes
M01029_1422	851.422	1.5mm Strut Plate, 2x36 holes
M01029_2263	852.263	2.0mm Oblique L-Plate, 6x4 holes, left
M01029_2264	852.264	2.0mm Oblique L-Plate, 6x4 holes, right
M01029_2420	852.420	2.0mm Strut Plate, 2x10 holes
M01029_2421	852.421	2.0mm Strut Plate, 2x18 holes
M01029_1320	851.320	1.5mm Double Y-Plate, 10 holes
M01029_1343	851.343	1.5mm Y-Plate, 4x3x3 holes
M01029_2110	852.110	2.0mm Orbital Rim Plate, 10 holes
M01029_2343	852.343	2.0mm Y-Plate, 4x3x3 holes
M01029_1008	851.008	1.5mm Adaption Plate, 8 holes
M01029_1012	851.012	1.5mm Adaption Plate, 12 holes
M01029_1020	851.020	1.5mm Adaption Plate, 20 holes
M01029_2008	852.008	2.0mm Adaption Plate, 8 holes
M01029_2012	852.012	2.0mm Adaption Plate, 12 holes
M01029_2020	852.020	2.0mm Adaption Plate, 20 holes

- The following plate was updated. A bevel was added to the outer edge and a shallow groove to the center of the top surface in order to give the surgeon tactile feedback indicating the top side of the plate. The addition of these features required that the plate become 0.5mm wider and, 0.5mm longer in order to maintain similar strength. The plate thickness remained the same.

Old Part Number	AO Part Number	Description
M01029_1604	851.604	1.5mm X-Plate, 4 holes

- The following Mesh Plates were updated. A bevel was added to the outer edge and shallow grooves to the top surface in order to give the surgeon tactile feedback indicating the top side of the plate. The plate's overall size and thickness remained the same.

Old Part Number	AO Part Number	Description
M01029_1520	851.520	1.5mm Mesh 50x50x0.8 thk
M01029_5010	851.721	1.5mm Straight Row Mesh 50x50x0.8 thk
M01029_5011	851.722	1.5mm Straight Row Mesh 100x100x0.8 thk
M01029_1520	852.520	2.0mm Mesh 48x48x1.2 thk
M01029_1522	851.522	1.5mm Mesh 125x125x0.8 thk
M01029_1521	851.521	1.5mm Mesh 100x100x0.8 thk
M01029_1521	852.521	2.0mm Mesh 78x78x1.2 thk

Conclusion regarding changes to plates:

- Plate strength was retained with this design change as shown below.

Plate Part Number	Average Strength from 510k Testing- 0 Time	Average Strength from Product Quality Testing- 0 Time	Average Strength from 510k Testing- 8 Weeks	Average Strength from Product Quality Testing- 8 Weeks
851.008	7.78 N	9.31 N	6.64N	8.30 N

- These changes aid the surgeon in identifying the correct orientation (top side up), therefore, maintaining a low profile. This, in turn, increases patient comfort. Strength, safety, efficacy, indications or marketing claims of the device are not adversely affected by these changes.

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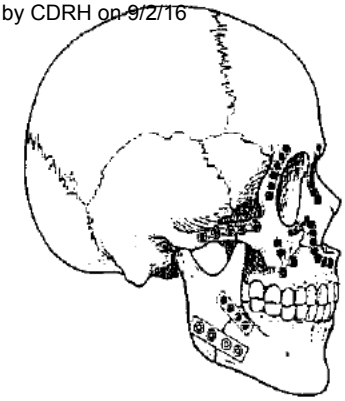
4(b) Engineering rationale dated August 13, 2003

SYNTHES Maxillofacial

August 13, 2003



To: Bonnie Smith

Cc: DHF Proj. M01-029

From: Ralph Zwirnmann 8/13/03

Re: Rationale for change of burr hole cover design from a disk to a pinwheel style

(b)(4) [redacted]

Plate Description	Volume (mm^3)
Synthes Contourable Mesh 150x150x1.2	(b)(4) [redacted]
Resorbable Burr Hole Cover, 10 Holes, 0.8mm Thick	

In conclusion, based upon the above listed facts, it is the opinion of Product Development that the new design of the burr hole cover poses no additional risks or hazards.

R. Zwirnmann
08/13/2003

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SYNTHES®
Maxillofacial

TO: Angela Silvestri

cc: Mike Chen; Joe Lanza

DATE: November 15, 2002

FROM: Doug Vaughen

RE: Comparison of Resorbable Mesh Volume

In response to the conference call with the FDA on November 13, 2002 I have prepared the following information to support our submission. This information includes material and volume comparisons between the new and predicate devices.

MATERIAL

The material of the new device is 70:30 Poly (L/DL-lactide). This is the same material as the predicate Synthes mesh and Macropore mesh. In addition, the Synthes meshes are machined from compression molded sheets that degrade by bulk hydrolysis and resorb completely in 24 - 36 months. In comparison, after examining samples of Macropore mesh, it appears that they have been manufactured in a similar process and claim degradation by bulk hydrolysis and resorb completely in 18 - 36 months. I would therefore anticipate that these implants would degrade similarly in-situ.

VOLUME

Solid models were created, by the use of Pro/ENGINEER 2002 from Parametric Technologies Company, representing the new Synthes Resorbable Contourable Mesh as well as the predicate resorbable mesh. From these models, the volume of each type of mesh was calculated and listed below. These values represent the actual volume of material for each type of mesh after machining the holes and slots. In addition, the overall volume was calculated. This represents the volume of material prior to milling the holes and slots into the sheet.

PREDICATE MESH	Actual Volume (mm^3)	Overall Volume (mm^3)	510(k)
Macropore Mesh			
120 mm x 120 mm x 2 mm	22,083	28,800	K000992 / K012413
120 mm x 120 mm x 1 mm	10,294	14,400	K983360
Synthes Mesh			
125 mm x 125 mm x 0.8 mm	9,218	12,500	K003786
PROPOSED MESH			
Synthes Contourable Mesh			
150 mm x 150 mm x 1.2 mm	11,032	27,000	Proposed

CONCLUSION

In reviewing the actual volume, it is apparent that the Synthes Contourable Mesh (150 mm x 150 mm x 1.2 mm) is approximately half of the volume of the Macropore Mesh (120 mm x 120 mm x 2 mm). It is also made of the same material. Therefore, the Synthes Resorbable Contourable Mesh is equivalent to the Macropore Mesh.

SYNTHES®

4(c) Engineering rationale dated April 9, 2004

Regulatory Pathway Form

Date: 09 April 04

Project Name / Project Numbers: Rapid Resorbable Plate Line Extension – Strut Plates with Scallops / M01-029

Product Description(s) / Product Number(s): _____

☐ List all here or _____ ☒ See attached pages

Predicate (System &/or part number): 1.5mm Resorbable Strut Plate 2x10 Holes / M01029-1420, 1.5mm Resorbable Strut Plate 2x18 Holes / M01029-1421, 1.5mm Resorbable Strut Plate 2x36 Holes / M01029-1422

1. Does the new system/product include a **Labeling Change** (compared to the predicate device)? ☒ Yes ☐ No

   Type of Change: (circle all that apply)
   - A. Clarity for safer use or effectiveness
   - B. Warnings and/or precautions
   - C. Indication for use
   - D. Addition/deletion of contraindication
   - E. New Part Number(s) / Description(s)

2. Does the new system/product include a **Technology or Performance Change** (compared to the predicate device)? ☐ Yes ☒ No

   Type of Change: (circle all that apply)
   - A. Performance specification
   - B. Dimensional specification
     - if **A** or **B** then,
       - > Does this affect indications for use? ☐ Yes ☐ No
       - > Does Product Development recommend clinical data to establish safety and effectiveness (to establish equivalence)? ☐ Yes ☐ No
       - > In Product Development's opinion, does any design validation (i.e. testing) raise issues of safety and effectiveness ☐ Yes ☐ No
   - C Packaging change
   - D. Sterilization change
     - if **D** then, does this include a change in performance specification or decrease in Sterility Assurance Level? ☐ Yes ☐ No

3. Does the new system/product include a **Material Change** (material type or formulation) (compared to the predicate device)?
   ☐ Yes ☒ No; if Yes then,
   - Is the part(s) considered an implant? ☐ Yes ☐ No (if Yes, skip to last bullet)
   - Will the part(s) with the material change be likely to contact body tissues or fluids in-vivo? ☐ Yes ☐ No
   - Is additional biocompatibility testing recommended? ☐ Yes ☐ No (See ISO 10993 for guidance)

Rationale as to why the above noted changes do not affect safety and efficacy of the system/product:
(Attach documentation that describes the project, including product/system req., drawings, risk/hazard analysis, test reports, etc.)
The plates listed below are identical to the predicate devices which are listed in the rapid resorbable fixation system 510k both dimensionally and in material (see attached prints). Therefore, there is no change to the safety or efficacy of the products.

☐ See attached rationale

(If rationale exceeds this space, attach additional pages to form)

Signature: Product Development _____ (Date) 4/9/04

Regulatory Decision:

US: 510(k) - ☐ Required ☒ Not Req. ☐ Exempt ☐ NA
IDE - ☐ Orig. Sub. ☐ Suppl. ☐ Suppl. Not Req. ☒ NA
PMA ☐ Original ☐ Suppl. ☐ 30 Day Report
☐ Annual Report ☒ NA

Canada: License ☐ Required ☐ Amend. Required ☐ Not Req.
☐ Clinical Study Auth. Required ☒ NA

Signature Sheri L. Musgrave Date 4/12/04

Regulatory Notes:
Official copy sent 4/12/04
DCO # _____
Applicable regulation(s): _____
21CFR 872.4760
Panel/Product Code: JEY

Product Description	Product Number
1.5mm Resorbable Strut Plate, Scalloped, 2x10 Holes	851.424
1.5mm Resorbable Strut Plate, Scalloped, 2x10 Holes, sterile	851.424.01s
1.5mm Resorbable Strut Plate, Scalloped, 2x18 Holes	851.425
1.5mm Resorbable Strut Plate, Scalloped, 2x18 Holes, sterile	851.425.01s
1.5mm Resorbable Strut Plate, Scalloped, 2x36 Holes	851.426
1.5mm Resorbable Strut Plate, Scalloped, 2x36 Holes, sterile	851.426.01s

(b)(4) Schematic drawing

(b)(4) Schematic drawing

(b)(4) Schematic drawing

(b)(4) Schematic drawing

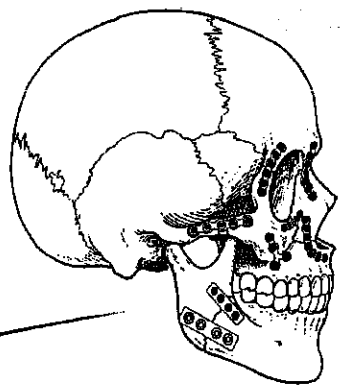
SYNTHES®

4(d) Engineering rationales dated February 2 and 6, 2006

SYNTHES

Polymer Development

2 February 2006



To: DHF USBIO-06001/ Rapid Resorbable Plate Line Extension

Cc:

From: Ralph Zwirnmann

2/2/06

Re: Rationale – Device Comparison Chart

-65-

The following is a comparison of additional devices for the Rapid Resorbable System to predicate devices. The Rapid Resorbable material (L-Lactide-co-glycolide), indications/contraindications for use along with size and volume ranges were previously approved in **510K #K030069**. No plates listed below exceed the size ranges or volumes approved within the previously mentioned 510K.

New Device			Predicate Device		
Non-Sterile Part Number	**Sterile Part Number**	**Description**	**Non-Sterile Part Number**	**Sterile Part Number**	**Description**
851.009	851.009.01s	1.5mm Rapid Resorbable Adaption Plate, Scalloped, 8 Holes	851.008	851.008.01s	1.5mm Rapid Resorbable Adaption Plate, 8 Holes
851.021	851.021.01s	1.5mm Rapid Resorbable Adaption Plate, Scalloped, 20	851.020	851.020.01s	1.5mm Rapid Resorbable Adaption Plate, 20 Holes

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		Holes			
851.724	851.724.01s	1.5mm Rapid Resorbable Straight Row Mesh 75x75x0.8mm	851.722	851.722.01s	1.5mm Rapid Resorbable Straight Row Mesh 100x100x0.8mm
851.436	851.436.01s	1.5mm Rapid Resorbable Strut Plate, Scalloped, 2x36 Holes	851.422	851.422.01s	1.5mm Rapid Resorbable Strut Plate, 2x36 Holes
851.344	851.344.01s	1.5mm Rapid Resorbable T-Plate, 3x3 Holes	851.343	851.343.01s	1.5mm Rapid Resorbable Y-Plate
851.500	851.500.01s	1.5mm Rapid Resorbable Box Plate, 4 Holes	851.520	851.520.01s	1.5mm Rapid Resorbable Mesh 50x50x0.8mm
851.605	851.605.01s	1.5mm Rapid Resorbable X-Plate, 8 Holes	851.006	851.006.01s	1.5mm Rapid Resorbable X-plate
852.265	852.265.01s	2.0mm Rapid Resorbable L-Plate, left, 2x2 Holes	852.263	852.263.01s	2.0mm Rapid Resorbable Oblique L-Plate, left
852.266	852.266.01s	2.0mm Rapid Resorbable L-Plate, right, 2x2 Holes	852.264	852.264.01s	2.0mm Rapid Resorbable Oblique L-Plate, right
851.689	851.689.01s	Orbital Floor Kit, 24mm w/ Template	821.699	821.699.01s	Orbital Floor Kit, 24mm w/ Template **(see rationale below)**
851.690	851.690.01s	Orbital Floor Kit, 30mm w/ Template	821.700	821.700.01s	Orbital Floor Kit, 30mm w/ Template **(see rationale below)**
851.691	851.691.01s	Orbital Floor Kit, 35mm w/ Template	821.701	821.701.01s	Orbital Floor Kit, 35mm w/ Template **(see rationale below)**
851.611	851.611.01s	1.5mm Rapid Resorbable Contourable Mesh 50x50x0.25mm	n/a	n/a	Previously approved in K030069
851.612	851.612.01s	1.5mm Rapid Resorbable Contourable Mesh 100x100x0.25mm	n/a	n/a	Previously approved in K030069
851.621	851.621.01s	1.5mm Rapid Resorbable Contourable Mesh 50x50x0.5mm	n/a	n/a	Previously approved in K030069

851.622	851.622.01s	1.5mm Rapid Resorbable Contourable Mesh 100x100x0.5mm	n/a	n/a	Previously approved in K030069
851.623	851.623.01s	1.5mm Rapid Resorbable Contourable Mesh 150x150x0.5mm	n/a	n/a	Previously approved in K030069
851.633	851.633.01s	1.5mm Rapid Resorbable Contourable Mesh 150x150x0.8mm	n/a	n/a	Previously approved in K030069

Rationale for Plate Line Extension:

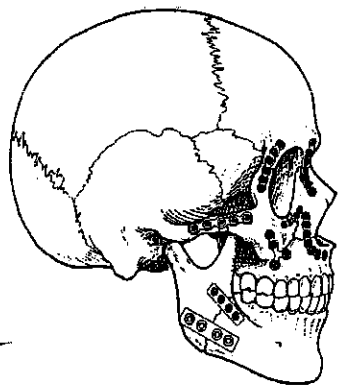
This plate line extension is in response to surgeons requesting additional rapid resorbable style plates and plates that have the same handling characteristics as the original resorbable plate line with the added benefit of a faster resorbing material.

Additionally, the previously released rapid resorbable orbital floor plates (851.540.01s, 851.541.01s, 851.542.01s) packaged or kitted with the previously released bending templates (329.632, 329.633, 329.634) which are similar to previously released kits 821.699.01s, 821.700.01s, and 821.701.01s have been requested. Since both the orbital floor plates and templates have been previously released; this is only an additional packaging configuration.

SYNTHES

Polymer Development

6 February 2006



To: DHF USBIO-06001/ Rapid Resorbable Plate Line Extension

Cc:

From: Ralph Zwirnmann 2/6/06

Re: Rationale – Device Comparison Chart2

-68-

The following is a comparison of additional devices for the Rapid Resorbable System to predicate devices. The Rapid Resorbable material (L-Lactide-co-glycolide), indications/contraindications for use along with size and volume ranges were previously approved in **510K #K030069**. No plates listed below exceed the size ranges or volumes approved within the previously mentioned 510K.

Rationale for Plate Line Extension:

This plate line extension is in response to surgeons requesting additional rapid resorbable style plates and plates that have the same handling characteristics as the original resorbable plate line with the added benefit of a faster resorbing material.

Additionally, the previously released rapid resorbable orbital floor plates (851.540.01s, 851.541.01s, 851.542.01s) packaged or kitted with the previously released bending templates (329.632, 329.633, 329.634) which are similar to previously released kits

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821.699.01s, 821.700.01s, and 821.701.01s have been requested. Since both the orbital floor plates and templates have been previously released; this is only an additional packaging configuration.

Device Comparison Chart

New Device **Synthes** **Rapid Resorbable Fixation System – Line Extension** **Poly (L-lactide-co-glycolide)**	**Predicate Device** **Synthes** **Rapid Resorbable Fixation System** **Poly (L-lactide-co-glycolide)** **(K030069)**	**Predicate Device** **W. Lorenz** **LactoSorb Trauma Plating System** **Poly (L-lactide-co-glycolide)** **(K960988, K971870, K992158, K003281)**
Design/Dimensions: **Plates** Meshes Thickness: 0.25, 0.5, 0.8 Shapes: square (50x50, 75x75,100x100, 150x150mm) Plates Screw hole diameter: 1.5 and 2.0mm Thickness: 0.8, 1.2mm Shapes: adaption, strut, L, T, X, Box	***Design/Dimensions:*** **Plates** Meshes Thickness: 0.25, 0.5, 0.8, 1.2mm Shapes: square (20x20 — 150x150mm) round (ø20 – 150mm) crescent (45 – 77mm in length) Plates Screw hole diameter: 1.5 and 2.0mm Thickness: 0.5, 0.8, 1.2mm Shapes: straight, adaption, orbital rim, orbital floor, oblique-L, strut, X, Y, burr hole cover.	***Design/Dimensions:*** **Plates** Mesh Panels/Sheets – K992158 Thickness: 0.25, 0.5, 0.75, 1.1mm Shapes: square (25x25 — 50x50mm) rectanglular (25x50mm) Plates – K960988, K971870 Screw hole diameter: 1.5 and 2.0mm Thickness: 0.8, 1.3mm Shapes: straight, orbital floor, square, oblique-L, T, X, Y.

SYNTHES®

Attachment 5:

Journal Articles

Summary of Articles

Losken A, MD; Williams J, MD; Burstein F, MD; Cohen S, MD; Hudgins R, MD; Boydston W, MD, PhD; Reisner A, MD; Simms C, RN. **Outcome Analysis for Correction of Single Suture Craniosynostosis Using Resorbable Fixation**. Journal of Craniofacial Surgery 2001; 12:425-455.

Supports Claim: *Resorbable implants are suitable for craniofacial reconstruction in the pediatric population.*

Clinical concerns about the permanent nature of metallic plates and screws in pediatric craniofacial reconstruction include growth restriction, implant migration, palpability, and interference with radiographic imaging post operatively. Due to the rapid healing of osteotomies in infants and children, the pediatric skeleton provides the ideal setting for the use of resorbable plates and screws, especially for remodeling of the facial and cranial bones.

In this study 63 patients were treated for correction of single-suture craniosynostosis using resorbable fixation. Average age was 22.7 months (range 2.8 months – 18 yrs.) Results suggest that resorbable plate and screws are as effective as titanium systems when treating single suture synostosis.

It was noted that the use of biodegradable plates and screws in the pediatric population has surpassed the use of metallic devices and is rapidly becoming the standard of care for reconstruction of the infant calvarium.

Kumar, A, MD; Staffenberg, D, MD; Petronio, J, MD; Wood, R, MD. **Bioabsorbable Plates and Screws in Pediatric Craniofacial Surgery: A Review of 22 Cases**. From the Section of Plastic, Reconstructive & Maxillofacial Surgery and Section of Neurological Surgery, Emory University School of Medicine, Atlanta, GA.

Supports Claim: *Resorbable implants are suitable for craniofacial reconstruction in the pediatric population.*

Potential problems with metallic plates and screws in the pediatric population include growth restriction and transcranial migration of hardware. Resorbable polymer plates retain sufficient rigidity until healing takes place. With the dissolution and gradual loss of tensile strength, growth restriction and potential migration are minimized.

In this study, 22 patients were treated for a variety of trauma and reconstruction issues. Patients ranged from 5 months to 288 months of age. All but one patient had satisfactory healing with no signs of infection or inflammation. One patient had lower eyelid erythema and edema at the 2 week follow up. The issue was resolved with oral antibiotics within 2 weeks.

Resorbable fixation is an attractive option for pediatric plastic and craniofacial surgery. With further experience this technique may become the standard of care in reconstruction of the infant calvarium.

Cappabianca, P, MD; Cavallo, L, MD; de Divitiis, E, MD. **Endoscopic Endonasal Transsphenoidal Surgery.** Neurosurgery, vol. 55, No. 4, October 2004, 933-940.

Supports Claim: *Resorbable plates are suitable for repair of the cranial skull base such as transsphenoidal surgery requiring sellar floor repair (example of clinical procedure).*

This article describes the endoscopic endonasal transsphenoidal procedure in detail. The sellar reconstruction segment is most relevant to the use of resorbable implants.

Sellar repair is generally performed when a CSF leak has occurred. The purpose of the repair is to create a protective barrier, reducing dead space and preventing the descent of the chiasm into the sellar cavity. Because of the endoscopic procedure is minimally invasive, autologous bone or cartilage from the nasal septum is usually unavailable. Synthetic or resorbable materials may be used to repair the sella safely and effectively.

Kaptain, G, MD; Vincent, D, MD; Laws, E, Jr., MD. **Cranial Base Reconstruction after Transsphenoidal Surgery with Bioabsorbable Implants: Technical Note.** Neurosurgery, vol. 48, No. 1, January 2001, 232-234.

Supports Claim: *Resorbable plates are suitable for repair of the cranial skull base such as transsphenoidal surgery requiring sellar floor repair (example of clinical procedure).*

Reconstruction of the cranial base is often necessary after transsphenoidal surgery to prevent cerebral spinal rhinorrhea and to maintain anatomic integrity. Sellar packing (fat, muscle, gelatin sponge) may be supported by bone or cartilage harvested at the time of surgery. The use of synthetic material becomes desirable in cases where autograft is not available.

Polylactide polymer implants are immunologically inert, magnetic resonance imaging – compatible, and easily contoured to custom-fit a defect. These implants are effective adjuncts in transspendoidal cranial base reconstruction when endogenous osseous or cartilaginous graft is unavailable due to repeat procedures or endoscopic surgery which does not expose the cartilaginous or bony septum.

It is anticipated that the bony growth at the cranial base/sellar defect will be complete by the time the plate is absorbed fully, within 2 years.

Clinical Notes

Outcome Analysis for Correction of Single Suture Craniosynostosis Using Resorbable Fixation

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Roger Hudgins, MD
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A retrospective review was performed on 63 patients at Childrens Healthcare of Atlanta at Scottish Rite who underwent correction of single-suture craniosynostosis using a resorbable fixation system. Included in the series were 24 patients with metopic synostosis, 15 with sagittal synostosis, and 24 with unicoronal synostosis. The average age at operation was 22.7 months (range: 2.8 months–18 years), and mean follow-up time was 30.7 months (range: 7.1–10 years). Reoperation equal to or exceeding the magnitude of the original procedure occurred in 4.76% of the patients. This was comparable to the reoperation rate observed at our institution using traditional fixation systems. Minor complications related to the use of resorbable plates were also identified, and the final outcome for single-suture synostosis was favorable. Results suggest that resorbable plates and screws are as effective as titanium-based systems in the treatment of single-suture synostosis.

Key Words: Craniosynostosis, single suture, resorbable fixation, titanium

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Effective management of craniosynostosis involves extensive cranial remodeling within the first year of life.[1] Microplating systems have become an integral part of pediatric craniofacial reconstruction, given their ability to provide structural integrity and support. Titanium plating systems have traditionally been used for rigid fixation because they are easy to apply, effective, and generally well tolerated. However, concerns about growth restriction, transcranial migration of the hardware, and the occasional infection or plate exposure have led to the search for alternative methods of fixation.[2–4]

Technical advances in plating systems have stimulated an evolutionary interest in the use of resorbable polymer plates and screws for craniofacial surgery. Since its introduction, rigid fixation using resorbable polymers has been used by many surgeons.[2–6] The ability of these plates to maintain sufficient rigidity until skeletal healing is complete has made them an attractive alternative for pediatric skeletal fixation. The ideal resorbable fixation system should not interfere with healing, should provide adequate stability throughout the process of bone healing, and should not cause any local or systemic side effects. During the past 2 decades it has become apparent in the literature that surgeons have been using this system with encouraging early results.[5–8]

Most of the initial applications were used in areas of minimal weight bearing; however, several reviews have discussed the use of resorbable fixation devices in areas of higher stress, as in facial fractures and mandibular advancements.[9–11] Likewise, we have used a resorbable plating system (Lactosorb,

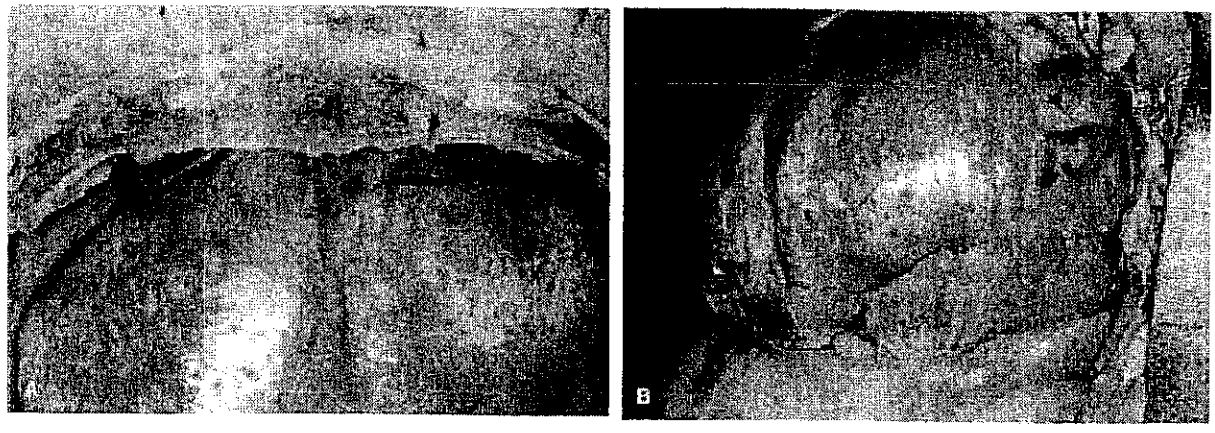

Fig 1 (A) Vertex view of the orbital bar after reshaping for unicoronal synostosis. Resorbable plates are used for rigid fixation of the midline. (B) Oblique view demonstrating the use of resorbable plates for lateral fixation.

Table 2. These reoperation rates were compared with historical control data previously presented from our institution using titanium plates and screws[12] (Table 3). Average interval time to reoperation was 2.4 years (range, 12 months–5.3 years).

Cost

The mean cost for initial hospitalization was $22,646 (range, $11,271–$47,951). Average charge for the Lactosorb implants was $6,663 (range, $3,007–$12,880), accounting for 29% of the total cost. Patients requiring reoperations had an additional cost, averaging $7,926 (range, $2,689–$18,091). Lactosorb accounted for 20% of the secondary reoperation costs. The mean hospitalization cost of $22,646 for Lactosorb patients was compared with a mean hospitalization cost of $24,846 for patients with titanium plates (data collected between November 1996 and November 1999).

Fig 2 The vertex view after the frontal bone has been reshaped and returned to the skull. Resorbable plates and screw were used anteriorly to secure the frontal bones to the orbital bar.

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the undesirable consequences of permanent titanium plates and screws. With the continued success of biodegradable plates and screws in the pediatric population, it has surpassed metallic devices as the plating system of choice and is quite rapidly becoming the standard of care for reconstruction of the infant calvarium.

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Bioabsorbable Plates and Screws in Pediatric Craniofacial Surgery: A Review of 22 Cases

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The purpose of this study was to evaluate the application of bioabsorbable fixation devices in reconstructive craniofacial procedures in the pediatric population. We reviewed 22 cases in which bioabsorbable plates and screws were used in craniofacial surgery for reconstruction. The procedures were performed in a 7-month period. The patients ranged in age from 5 to 228 months at the time of surgery (mean, 76.7 months). The postoperative clinical follow-up ranged from 2 to 16 weeks. The fixation devices were evaluated with regards to satisfactory fixation at the time of procedure. The postoperative follow-up evaluated clinical wound healing, signs of infection or local inflammation, and visibility or palpability of plates through the skin. All patients except one showed satisfactory wound healing with no sign of infection or local inflammation. The plates provided satisfactory fixation and were not visible through the skin. Two patients had plates that were palpable at the 4-month follow-up period. One patient with repair of a blow-out fracture of the orbit with resorbable mesh had redness and swelling over the wound site 2 weeks postoperatively with resolution 4 weeks postoperatively. Our early experience suggests reabsorbable fixation is an attractive option in pediatric plastic and craniofacial surgery. With further experience, this technology may represent the standard of care in reconstruction of the infant calvarium.

Key Words: Bioabsorbable fixation device, craniofacial reconstruction

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Metallic plates have become the workhorse of craniofacial surgery and have enabled surgeons to apply the principles of rigid fixation. Such fixation in the pediatric population is not without complications. In children, possible complications include growth restriction [1, 2] and transcranial migration of the hardware [2]. Because of these weaknesses, alternative techniques need to be available to the craniofacial surgeon.

One such alternative technique involves the application of resorbable polymer plates, which will retain sufficient rigidity until skeletal healing has taken place. Polylactic acid, polyglycolic acid, and polydioxanone have been studied clinically and experimentally in both adult [3–10] and immature [1] animals. These devices are completely resorbed by the process of hydrolysis within 9 to 14 months. With the dissolution and gradual loss of tensile strength of the devices [11], growth restrictions are minimized as is the potential for transcranial migration. Plates and screws composed of polylactic and polyglycolic acid have become commercially available, and clinical experience with these devices is rapidly expanding.

Patients and Methods

We have applied the LactoSorb system (Walter Lorenz Surgical, Inc., Jacksonville, FL) in 22 pediatric patients undergoing craniofacial reconstruction (Table). The procedures were performed in a 7-month period (April 10 to October 22, 1996). The patients ranged in age from 5 to 288 months at the time of surgery (mean, 76.6 months). Preoperatively, all patients underwent computed tomographic (CT) scans for evaluation and plain x-ray films when appropriate (i.e., traumatic fractures). The postoperative follow-up ranged from 2 to 16 weeks. The fixation devices were evaluated with regards to satisfactory fixation at the time of procedure. On postoperative follow-up, clinical wound healing, signs of infection or local inflammation, and visibility or palpability of plates through the skin were evaluated.

All patients received a preoperative dose of cephazolin. When a craniotomy was performed, drains were used

visible through the skin. In two patients plates were palpable at the 4-month follow-up visit. The one complication occurred in a 5-year-old boy who sustained an infraorbital rim and orbital floor fracture in a motor vehicle accident. The patient underwent ORIF of the fracture with resorbable mesh. The patient was noted to have lower lid erythema and edema at the 2-week follow-up visit with complete resolution after 2 more weeks with oral antibiotics.

Conclusion

Our early experience suggests that reabsorbable fixation is an attractive option in pediatric plastic and craniofacial surgery. All cases resulted in satisfactory fixation. Although we did not specifically measure this, we believe that the time required to apply these devices was no longer than that required for standard fixation devices. With further experience, this technology may come to represent the standard of care in reconstruction of the infant calvarium.

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ENDOSCOPIC ENDONASAL TRANSSPHENOIDAL SURGERY

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ONLINE DIGITAL VIDEO

THE ENDOSCOPIC ENDONASAL TRANSSPHENOIDAL approach is a minimally invasive surgical technique for the removal of sellar and parasellar lesions. The procedure is performed via an anterior sphenoidotomy. The two main characteristics of the endoscopic approach, when compared with the standard microsurgical operation, arise from the use of the endoscope as a unique optical device and from the absence of a transsphenoidal retractor. More convenient straight surgical instruments are employed, whereas bayonet-shaped tools are used in the microsurgical procedure, to avoid any interference with the light beam generated by the microscope. The standard surgical technique is composed of three main time phases: the nasal, sphenoid, and sellar phase. During the nasal phase, the scope is introduced through the chosen nostril and advanced up to the sphenoethmoid recess, where the sphenoidotomy is performed. The sphenoid phase consists of the detachment of the nasal septum from the sphenoid rostrum, the anterior sphenoidotomy, removal of the sphenoid septum or septa, and identification of the landmarks inside the sphenoid sinus. In the sellar phase, an opening of the sellar floor is performed for removal of the lesion. A wide view of the sellar environment is obtained through angled scopes to detect eventual tumor remnants. The procedure ends with the reconstruction of the sella and removal of the endoscope from the nostril, without any postoperative nasal packing.

KEY WORDS: Endoscopy, Instrumentation, Minimal invasive surgery, Sellar tumors, Pituitary adenoma, Transsphenoidal surgery

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During the past decade, endoscopic transsphenoidal surgery, a minimal invasive transsphenoidal approach performed with an endoscope as a stand-alone visualizing and operating instrument, has been progressively accepted by surgeons and patients. In many centers throughout the world, this technique is now routinely used under the same indications as conventional microsurgical technique.

In 1963, Guiot et al. (11) first proposed the use of the endoscope as part of the transnasorhinoseptal microsurgical approach to explore the sellar contents. However, this idea remained unrecognized until the further contribution of Apuzzo et al. (1) in 1977. The use of the endoscope in transsphenoidal surgery was reconsidered as a result of advances in optical technology that permitted the development of adequate endoscopic instrumentation and the widespread use of endoscopes in nasal and paranasal sinus surgery by otolaryngologists. Some authors have described an endoscope-assisted technique, i.e., the use of the endoscope to complement the microscope in the early or late stages of a traditional procedure. "Pure" endoscopic endonasal transsphenoidal surgery, with the endoscope used alone throughout the approach to visualize the surgical trajectory and the surgical target area, has been described in detail by Jho et al. (12). This represents a newly established technique, well defined in its main aspects, which we have used in nearly 300 patients (9). It permits panoramic vision, close to the surgical target and within the relevant anatomy (7, 8), with minimal trauma and a low complication rate (3).

EQUIPMENT

The two main characteristics of the endoscopic approach, if compared with the standard microsurgical operation, arise from the use of the endoscope itself and from the absence of the transsphenoidal retractor. These

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two characteristics determine the need for proper endoscopic equipment and specially designed surgical tools.

The endoscopic equipment consists of different components: the endoscope, the fiberoptic cable, the light source, the camera, the monitor, and the video recording system. The picture that is displayed on the screen is the result of all these interconnected devices and represents the only view of the surgical field for the surgeon and others involved in the surgical procedure.

The components can be compared with a clock mechanism: if one part does not work well, it will influence all of the others. Therefore, the final quality of intraoperative images will be determined by the lowest-quality element in the system. The outcome of the surgical procedure also will depend on the quality of the endoscopic equipment. Thus it is essential that the best available endoscopic equipment is used, and the function of every component checked carefully, before the operation begins.

The commonly used endoscope is a rigid scope 4 mm in diameter, 18 or 30 cm in length, and with 0-degree, 30-degree, and 45-degree lenses, according to the different steps of the surgical operation. Smaller endoscopes that are 2.7 mm in diameter can be used, especially in children and in patients with very narrow nostrils. The endoscope must be introduced in a sheath, connected to a cleaning-irrigation system, and controlled by a manual or foot switch. The irrigation system permits cleaning of the distal lens, thus avoiding repeated entrances and exits from the nostril.

The endoscope is connected to a cable, which is made of a fr bundle of optical fibers capable of high-quality optical tra- mission. The cable must be handled carefully to avoid twisting and fracturing the optical fibers.

The cable is connected to a light source. Xenon cold light is the state of the art, because it has spectral characteristics close to sunlight, and the illumination it provides is whiter than halogen light.

A digital video camera must be used, preferably a three-charge-coupled device camera, which offers significantly enhanced sharpness and contrast of the video images compared with a mono charge-coupled device camera. With a three-charge-coupled device camera, a high-resolution monitor (>750 lines) must be used to support the high resolution of the camera. For image and video documentation, a digital recording system is preferable rather than a standard VHS or S-VHS system.

The surgical instruments are different from those used in a microsurgical approach, in which the bayonet shape is needed to avoid conflict between the hands of the surgeon and the lens of the microscope. In the endoscopic approach, straight instruments are preferable as they can be inserted close to the endoscope along its axis. The instruments are equipped with differently angled tips so that the surgeon can manage all areas visible as a result of the wider view afforded by the endoscope. Some instruments have been derived from the otorhinolaryngological experience in endoscopic nasal and paranasal sinus surgery, and others have been specifically designed for the endoscopic transsphenoidal approach; this aspect continues to evolve.

An endoscope holder is used to provide stability to the endoscope during the sellar phase of the procedure, thus freeing both of the surgeon's hands and giving the surgeon a fixed image of the operating field. Furthermore, it reduces the number of recurrent in-and-out movements, thus saving surgical time.

The use of C-arm fluoroscopy, which is routine in the course of the microsurgical transsphenoidal approach, has been progressively abandoned after adequate experience and is reserved for patients with presellar or conchal-type sphenoid sinuses. The use of a neuronavigation system can be helpful to assist in the identification of the anatomic landmarks, particularly in patients with recurrent tumors (13).

STANDARD SURGICAL PROCEDURE
(see video at web site)

Operating Room

The procedure shown in the accompanying video was performed by the senior author (EdD). The endoscopic equipment (monitor, light source, video camera, video recorder) is ergonomically positioned behind the head of the patient and in front of the operator, who is at the right side of the patient. The anesthetist is positioned with his or her equipment at the left side of the patient at the level of the head. The assistant is at the left side of the patient, and the nurse is positioned at the level of the patient's legs. The table-mounted endoscope holder is fixed next to the patient's shoulder and is tilted so as not to interfere with the maneuvers of the surgical instruments.

Patient Positioning

Under general anesthesia with orotracheal intubation, the patient is positioned supine with the trunk elevated 10 degrees and the head turned 10 degrees toward the surgeon and fixed with tape in a Mayfield headrest without pins. The inclination of the head in the vertical plane varies as a function of the anatomy of the lesion. If the lesion is primarily in the sphenoid sinus or the clivus, the head is slightly flexed, whereas in lesions that extend toward the suprasellar region or the planum sphenoidale, the head of the patient is left in a neutral position slightly hyperextended. These variations of the inclination of the head are needed to avoid a situation in which the endoscope is positioned too close to the chest, interfering with the maneuvering of the surgical instruments, or too high, where it could increase the risk of accidentally dropping instruments. The nasal cavities are packed with gauze pledgets soaked in a diluted solution of 5% chlorhexidine gluconate, the face and the nose are prepared with the same agent, and then the patient is aseptically draped.

Nasal Phase

Close Collaboration with the Anesthesiologist

Before beginning the surgical procedure, the anesthesiologist helps to ensure bloodless nasal cavities, by means of a slight controlled hypotension and excellent analgesia to minimize mucosal bleeding, especially until the anterior sphenoidotomy has been performed. It is better to wait an additional 5 to 10 minutes until the anesthesiologist has adjusted each parameter, than to start the surgical procedure and contend with bleeding from the nasal mucosa.

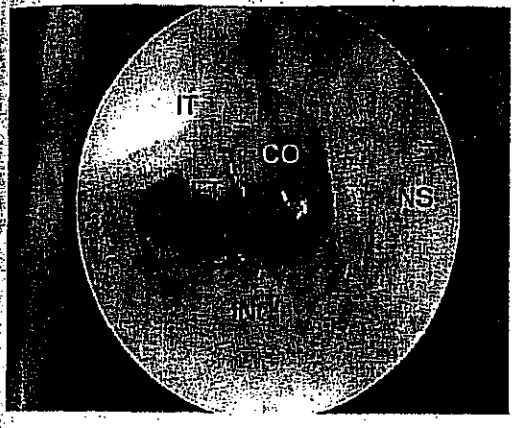

FIGURE 1. *Right nostril approach, nasal phase of the procedure, showing identification of the landmarks along the floor of the nasal cavity.* FNC, *floor of the nasal cavity;* NS, *nasal septum;* ET, *eustachian tube;* IT, *inferior turbinate;* CO, *choana;* SER, *sphenoethmoid recess.*

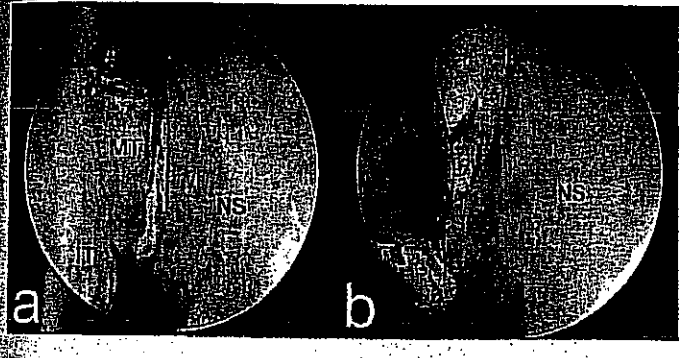

FIGURE 2. *Right nostril approach, nasal phase of the procedure.* a, *positioning of a cottonoid between the middle turbinate and the nasal septum.* b, *lateralization of the middle turbinate with an elevator and exposure of the sphenoethmoid recess.* NS, *nasal septum;* IT, *inferior turbinate;* MT, *middle turbinate.*

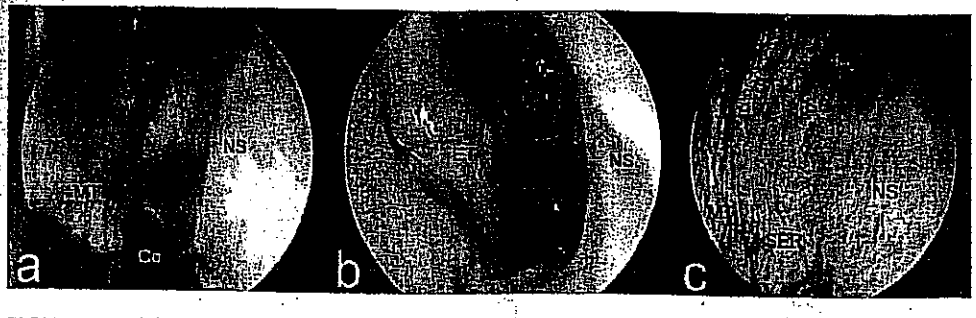

FIGURE 3. *Right nostril approach, nasal phase of the procedure.* a, *exploration of the inferior part of the nasal cavity and identification of the tail of the middle turbinate and of the choana.* b, *view of the anatomic structures through the choana.* c, *exploration of the superior part of the nasal cavity and identification of the sphenoid ostium.* NS, *nasal septum;* MT, *middle turbinate;* SER, *sphenoethmoid recess;* Co, *choana;* ST, *superior turbinate;* ET, *eustachian tube;* RPX, *rhinopharynx;* SP, *soft palate,* SO, *sphenoid ostium.*

Identification of Landmarks Inside the Nasal Cavity

The endoscope (4 mm in diameter, 0-degree angled lens, 18 cm in length) is introduced through the chosen nostril, tangential to the floor of the nasal cavity. The first structures to be identified are the inferior turbinate laterally and the nasal septum medially. Above the inferior turbinate the head of the middle turbinate can be observed; usually it is close to the nasal septum. As the endoscope advances along the floor of the nasal cavity, it reaches the choana. Its medial margin is the vomer, which confirms the midline of the approach, and its roof is shaped by the inferior wall of the sphenoid sinus. Lateral to the choana is the tail of the inferior turbinate (*Fig. 1*).

Lateral Luxation of the Middle Turbinate

Cottonoids soaked with diluted adrenaline (1:100000) or with xylometazoline hydrochloride are positioned between the middle turbinate and the nasal septum to enlarge the space between them and obtain decongestion of the nasal mucosa, which has rich innervation and vascularization (*Fig. 2A*). The head of the middle turbinate is delicately dislocated laterally to further widen the virtual space between the middle turbinate and the nasal septum and to create an adequate surgical pathway. The maneuver for laterally dislocating the head of the middle turbinate is performed, and the middle turbinate is protected with cottonoid to avoid any mucosal laceration (*Fig. 2B*).

Identification of the Sphenoid Ostium

After the creation of adequate space between the middle turbinate and the nasal septum, the endoscope is angled upward along the roof of the choana and the sphenoethmoid recess until it reaches the sphenoid ostium, usually located approximately 1.5 cm above the roof of the choana (*Figs. 3* and *4*). The sphenoid ostium is extremely variable in shape, size, and position. If the sphenoid sinus and the sphenoid rostrum are well pneumatized, the ostium appears situated laterally, covered by the superior or supreme turbinate and thus not initially visible. In these cases, the superior and/or supreme turbinate can be gently lateralized or removed, protecting the lateral lamella of the cribriform plate on which these turbinates are inserted. It is important to bear in mind that the roof of the ethmoid is composed of two components: a

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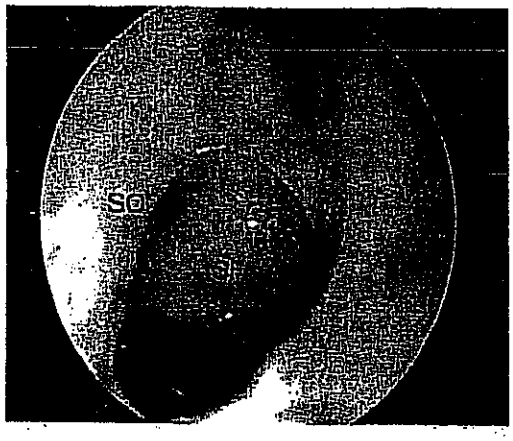

FIGURE 4. *Right nostril approach, nasal phase of the procedure, showing a view of the sellar floor through a natural sphenoid ostium. SO, sphenoid ostium; SF, sellar floor.*

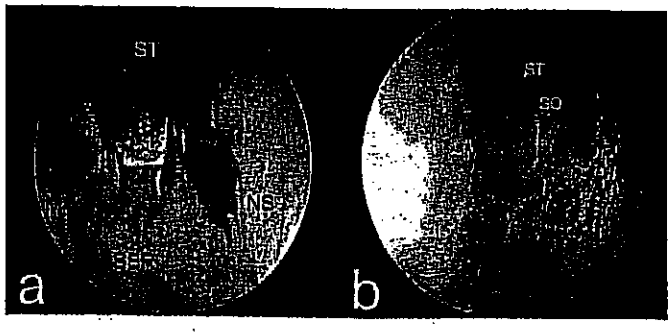

FIGURE 5. *Right nostril approach, sphenoid phase of the procedure. a and b, coagulation of the sphenoethmoid recess and of the area around the sphenoid ostium by means of a monopolar electrode. NS, nasal septum; MT, middle turbinate; SER, sphenoethmoid recess; ST, superior turbinate; SO, sphenoid ostium.*

superolateral roof (frontal bone) made of thick bone and a superomedial wall (ethmoid bone) composed of a thin bone, the so-called lateral lamella of the cribriform plate. The more elongated the lateral lamella, the greater the risk of damage to the cribriform plate during the removal or the lateral luxation of these turbinates, thus causing an ethmoid cerebrospinal fluid (CSF) leak.

If the sphenoid ostium is not visible, once the choana is identified to gain access to the sphenoid cavity, the endoscope is ascended along the sphenoethmoid recess for approximately 1.5 cm, between the superior turbinate and the nasal septum. Pressure with a blunt instrument then is exerted to create access to the sphenoid cavity.

Sphenoid Phase

Coagulation of the Sphenoethmoid Recess

Once the sphenoid cavity is reached, coagulation of the sphenoethmoid recess and the area around the sphenoid ostium is performed, starting approximately 0.5 cm from the top of the choana up to the superior border of the nasal cavity. This serves to avoid arterial bleeding originating from septal branches of the sphenopalatine artery (*Fig. 5*).

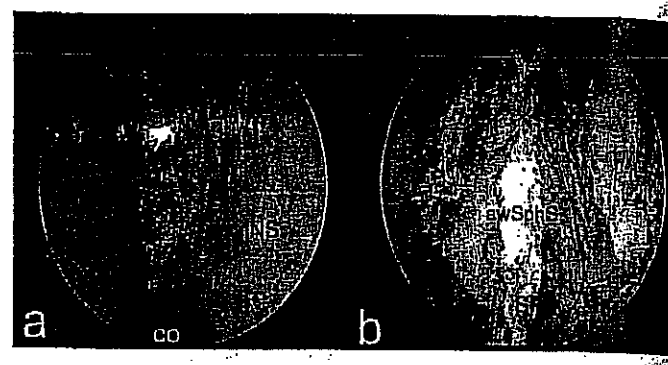

FIGURE 6. *Right nostril approach, sphenoid phase of the procedure. a, detachment of the nasal septum from the sphenoid rostrum by means of a microdrill with cutting burr. b, exposure of the anterior wall of the sphenoid sinus. NS, nasal septum; MT, middle turbinate; SER, sphenoethmoid recess; CO, choana; SP, sphenoid prow; awSphS, anterior wall of the sphenoid sinus.*

Detachment of the Nasal Septum from the Sphenoid Rostrum

At this point in the procedure, a microdrill with a cutting burr is used to separate the nasal septum from the sphenoid rostrum (*Fig. 6*). When sellar lesions extend inside the sphenoid cavity, occupying most of it, it is necessary to modify this step. When the sellar lesion does not occupy the sphenoid sinus after the detachment of the nasal septum and removal of the anterior wall of the sphenoid sinus, there is sufficient working room for the endoscope and instruments inside the sphenoid cavity. However, when the sellar lesion has expanded inside the sphenoid cavity, there is insufficient working room to maneuver the instruments. Under these circumstances, the initial coagulation of the sphenoethmoid recess is extended to the posterior part of the nasal septum, which is then drilled and removed for approximately 1 cm. In this fashion, after the anterior sphenoidotomy, new working space is created between the sellar floor in the sphenoid cavity and the nasal septum.

Enlargement of the Anterior Sphenoidotomy

The entire anterior wall of the sphenoid sinus has been made visible, and enlargement proceeds circumferentially by use of bone punches or a microdrill (*Fig. 7*); care must be taken in the inferolateral direction, where the sphenopalatine artery or its major branches lie. To avoid these vessels, it is sufficient to cut away the nasal mucosa slightly in an inferolateral direction and to coagulate it with the bipolar forceps, completely exposing the sphenoid rostrum.

The sphenoid rostrum is then removed in fragments and not *en bloc*, as this last maneuver could cause lacerations and bleeding in the nasal mucosa during passage through the nasal cavity. It is mandatory to remove the anterior wall of the sphenoid sinus widely, especially downward, before reaching the sella; otherwise, the instruments will not be able to reach all the areas visible by the endoscope. Once the anterior sphenoidotomy is completed, small amounts of bleeding originating from the edges of the sphenoidotomy must always be checked to avoid occluding the lens of the endoscope during the upcoming phases.

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FIGURE 7. *Right nostril approach, sphenoid phase of the procedure.* a, *enlargement of the anterior sphenoidotomy with bone punches.* b *and* c, *exposure of the sphenoid cavity with partial removal of the sphenoid septa. SF, sellar floor; ST, superior turbinate; C, clivus; *, sphenoid septum.*

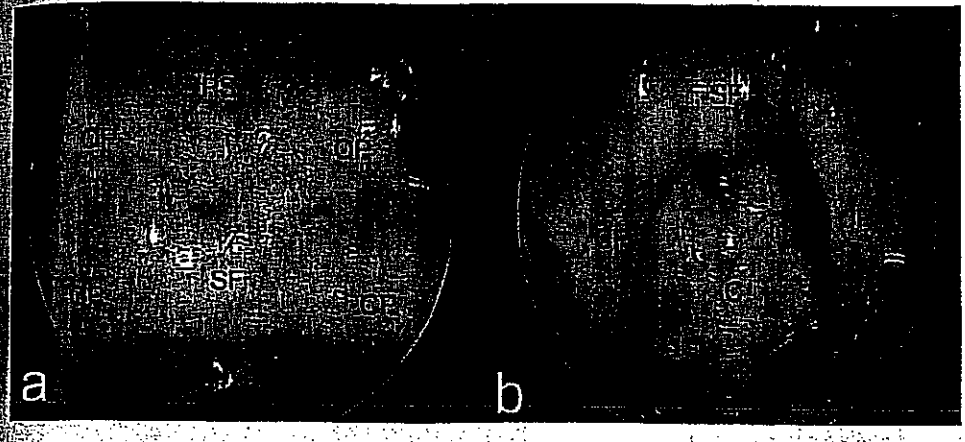

FIGURE 8. *Right nostril approach, sphenoid phase of the procedure.* a *and* b, *identification of the landmarks inside the sphenoid sinus.* SF, *sellar floor;* CP, *carotid protuberance;* C, *clivus;* PS, *planum sphenoidale;* OP, *optic protuberance;* OCR, *optocarotid recess.*

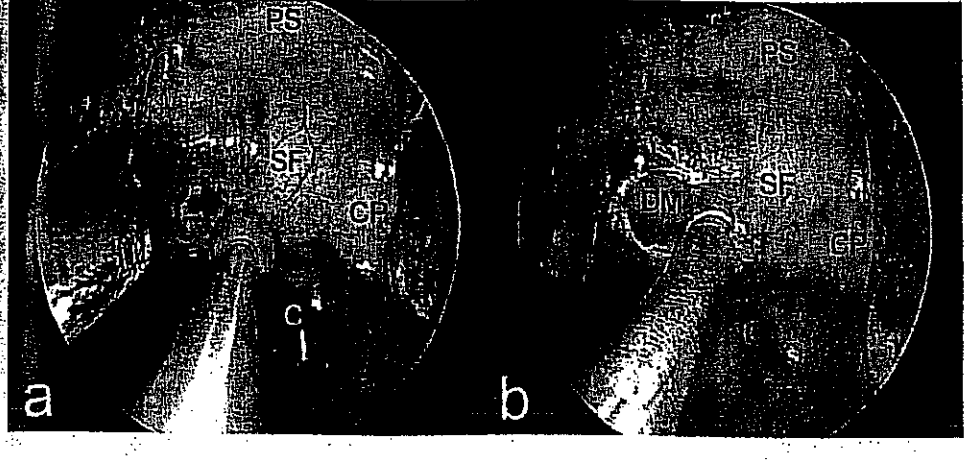

FIGURE 9. *Right nostril approach, sellar phase of the procedure.* a, *opening of an intact sellar floor by means of microdrill with diamond burr.* b, *enlargement of the sellar opening by means of a bone-cutting punch.* SF, *sellar floor;* CP, *carotid protuberance;* C, *clivus;* PS, *planum sphenoidale;* DM, *dura mater.*

Removal of the Sphenoid Septum

After the anterior sphenoidotomy has been performed, one or more septa can be identified inside the sphenoid sinus. The images of the sphenoid sinus septations revealed by the preoperative computed tomographic scan (in coronal and axial projections) must be compared with the endoscopic views, especially when the septa are implanted on the carotid prominences and the sphenoid sinus is a presellar type. The insertion of the septum/septa along the posterior wall of the sphenoid sinus may be a useful anatomic landmark for identification of the edges of the sellar floor. Although in selected patients it is not necessary to remove all the sphenoid septa, in most cases removal must be as complete as possible, from the planum to the clivus, to expose all the anatomic findings visible inside the sphenoid cavity. The removal of the sphenoid septa must be performed with cutting bone punches, avoiding detachment of the sphenoid mucosa, unless adenomatous infiltration is evident or suspected.

Identification of Landmarks Inside the Sphenoid Sinus

After removal of the sphenoid septa, the posterior and lateral walls of the sphenoid sinus are visible, with the sellar floor at the center, the sphenoethmoid planum above it, and the clival indentation below. Lateral to the sellar floor, the bony prominences of the intracavernous carotid artery and the optic nerve can be observed; between them the optocarotid recess, molded by the pneumatization of the optic strut of the anterior clinoid process, is visible (*Fig. 8*). These prominences and depressions, especially in a well-pneumatized sphenoid sinus not invaded by a sellar lesion, define a sort of "fetal face," where the forehead corresponds to the sphenoid planum, the eyes to the two optocarotid recesses, the eyebrows to the two optic nerves, the nose to the sella, and the mouth to the clivus, laterally limited by the two paraclival carotid arteries representing the cheeks.

In the majority of sellar-type sphenoid sinuses, all these landmarks may not be recognizable. However, the identifica-

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FIGURE 10. *Right nostril approach, sellar phase of the procedure, showing dural incision with a knife.* DM, *dura mater;* CP, *carotid protuberance;* C, *clivus.*

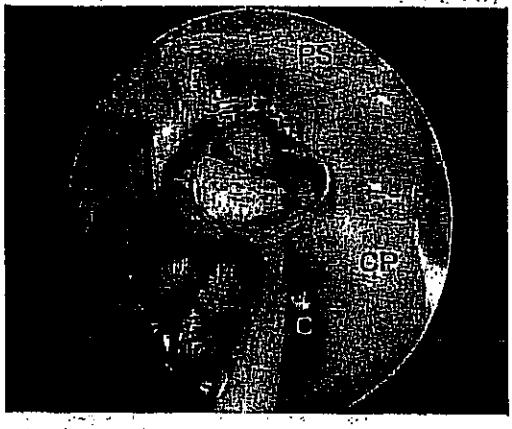

FIGURE 11. *Right nostril approach, sellar phase of the procedure, showing removal of the lesion with a curette.* CP, *carotid protuberance;* C, *clivus;* PS, *planum sphenoidale.*

tion of the sphenoethmoid planum, the clival indentation, and the bony protuberances of the intracavernous carotid artery can be considered enough to determine the edges of the sellar floor safely.

In the presence of a presellar or a conchal sphenoid sinus, there will be a paucity of anatomic landmarks. The use of a neuronavigation system will aid in avoiding lateral misdirection close to the parasellar and paraclival courses of the internal carotid arteries.

Sellar Phase

Opening of the Sella

From this phase of the procedure, a longer endoscope (4 mm in diameter, 0-degree angled lens, 30 cm in length) fixed to the holder is positioned inside the nasal cavity. This frees both of the surgeon's hands and allows comfortable introduction of two instruments under the endoscope, without coming into conflict with it.

FIGURE 12. *Right nostril approach, sellar phase of the procedure, showing exploration of the sellar cavity after the removal of the lesion.* SC, *suprasellar cistern;* DM, *dura mater;* SF, *sellar floor;* C, *clivus.*

The sellar phase of the endoscopic procedure must follow the already well defined rules of the microsurgical transsphenoidal approach (10). The opening of the sellar floor can be performed in different ways and with different tools (bone punches or microdrill) and must be extended as required by the specific pathological entity, if necessary reaching the sphenoid planum above, the clivus below, and the anterior limits of the cavernous sinuses bilaterally. During this maneuver, care must be exercised to avoid compromising the underlying dura (*Fig. 9*).

The dura is incised in a midline position and in a linear, rectangular, or cruciate fashion (*Fig. 10*). The superior and inferior intercavernous sinuses are usually compressed and obliterated in patients with macroadenomas, making the dural incision bloodless; in microadenomas and especially in Cushing disease, however, the entire sellar dura may be covered by one or two venous channels, which can bleed during the dural incision. To avoid such an event, a small dural incision is initially performed until the venous sinus is reached. Then the intercavernous sinus is secured and sealed with bipolar coagulation forceps or with two small surgical clips placed across it, and the dura then can be safely incised. Caution is necessary when incising the dura in patients with microadenomas to avoid damaging a possibly ectatic carotid artery that may be located within the sella, especially in acromegalic patients.

Removal of the Lesion

During removal of microadenomas, it is advisable not to position the endoscope too close to the sellar cavity with the purpose of obtaining a closer view of the surgical field. The instruments and the endoscope will converge on the same target in conflict with each other (*Fig. 11*).

The removal of macroadenomas should be accomplished sequentially. The inferior and lateral fragments of the lesion should be removed before the superior aspect. Removal of the superior part of the macroadenoma first will prematurely deliver the redundant diaphragma into the operative field, which will obscure visualization of the lateral portions and reduce the possibility of radical removal of the adenoma. After

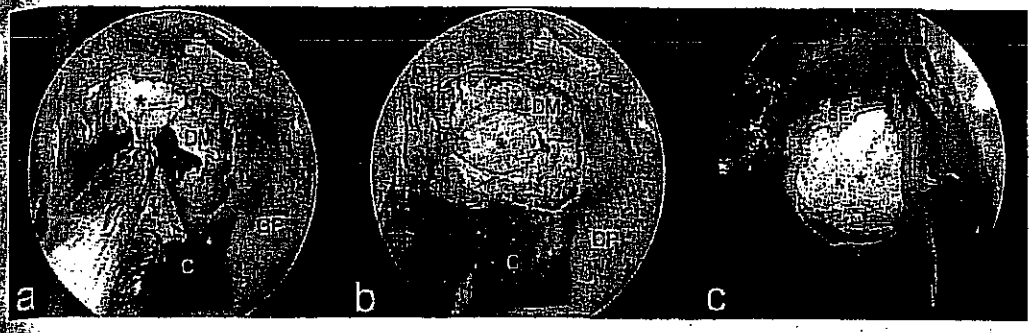

FIGURE 13. *Right nostril approach, sellar phase of the procedure.* a, *sellar repair with dural substitute introduced in a bent fashion through the nostril and then released intra-* (b) *or extradurally* (c). CP, *carotid protuberance;* C, *clivus;* DM, *dura mater;* SF, *sellar floor;* *, *dural substitute.*

the removal of the macroadenoma, if the descent of the suprasellar portion of the lesion is not observed, it is useful to perform a Valsalva maneuver, which may encourage protrusion of the suprasellar cistern into the sellar cavity (*Fig. 12*). If there is enough space in the sellar cavity, angled 30-degree and 45-degree endoscope are then advanced sequentially into the tumor cavity to verify the presence of any tumor remnants, which often are imprisoned in the recesses created by the fall of the suprasellar cistern.

When the lesion extends toward the medial wall of the cavernous sinus, its removal can be accomplished, under endoscopic control, by use of curved suction cannulas. The venous bleeding that might occur can be controlled by temporarily positioning hemostatic substances and cottonoids and by gently compressing the medial wall of the cavernous sinus and irrigating for a few minutes.

After intracapsular emptying of the adenoma, its pseudocapsule can be dissected from the suprasellar cistern. It must to taken into account that as a macroadenoma grows, it often stretches the residual anterior pituitary tissue, such that it appears as a thin layer of tissue surrounding the adenoma, the removal of which could cause postoperative hypopituitarism.

Inside a well-pneumatized sphenoid sinus, the endoscope allows the surgeon to visualize many structures including the planum sphenoidale, the clivus, the carotid and optic protuberances, and the cavernous sinus compartment. Thus, some lesions arising or extending into these regions, such as suprasellar craniopharyngiomas, tuberculum sellae meningiomas, macroadenomas involving the cavernous sinus, and upper clival chordomas, can be resected through such an approach. Nonetheless, the use of the endoscopic approach for the removal of these lesions must be reserved for experienced neurosurgeons because in such cases, the necessary modifications to the standard approach, indications, and limits are not yet standardized.

Sellar Reconstruction

Once the sellar lesion has been removed, a sellar repair is performed in selected patients, mainly when an intraoperative CSF leak has occurred. Various techniques are used (intra- and/or extradural closure of the sella and packing of the sella with or without packing of the sphenoid sinus) (5). Because of the minimal invasiveness of the endoscopic procedure, which avoids incision and dissection of the oral or nasal mucosa, autologous bone or cartilage from the nasal septum usually is unavailable. Therefore, synthetic or resorbable materials, as necessary, must be used to perform safe and effective repair of the sella (*Fig. 13*).

Repair of the sella is performed with the purpose of creating a protective barrier, reducing the dead space, and preventing the descent of the chiasm into the sellar cavity. Overpacking of the sella must be avoided to prevent compression of the optic system. Lumbar drainage is used in the event of an intraoperative CSF leak, when the closure is not judged watertight, in extended approaches, or when a minimal, unexpected postoperative CSF leak occurs.

At the end of the procedure hemostasis is obtained, final irrigation is performed, the endoscope is removed gradually, and the middle turbinate is gently restored in a medial direction as contact with the nasal septum is avoided to prevent the formation of synechiae. Packing of the nasal cavity is not considered necessary except in the event of diffuse intraoperative bleeding from the nasal mucosa, as can occur in some acromegalic patients or in poorly controlled hypertensive patients, in which case it is applied for a few hours.

At discharge, the patient is instructed to use an antibiotic salve in the nasal vestibule and to irrigate the nasal cavities with a seawater solution three times daily for 7 days, which will clear away small blood clots inside the nasal cavities and prevent possible endonasal synechiae. The patient is referred to an endocrinologist for follow-up and is reexamined in the outpatient clinic at 15 days and at 3 months postprocedure. In patients with preoperative visual field defects, the 3-month follow-up examination is preceded by sine and contrast-enhanced MRI scans of the sella and visual field examination. All data are collected and stored in a dedicated database.

The endoscopic procedure is a young technique that is well defined in its main aspects. Even taking into account the learning curve for a new procedure, preliminary results seem encouraging (4). We have observed an overall decreased incidence of complications (3) as compared with large historical series of traditional transsphenoidal microsurgery (6); this probably is attributable to the overview inside the anatomy that the endoscope permits and to decreased surgical trauma. Other advantages of the endoscopic approach are the easier treatment of recurrences (2) and a reduced postoperative stay (9), which is particularly notable in patients with nonsecreting pituitary adenomas, which usually present easier endocrinological postoperative management. The biology of pituitary

adenomas requires further study before definitive conclusions can be drawn regarding the effectiveness of this type of surgical treatment.

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Acknowledgments

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COMMENTS

Cappabianca et al. provide a description of their technique of endoscopic endonasal transsphenoidal surgery. The endoscopic technique has been gaining in popularity in recent years. I believe that Dr. Cappabianca has been a leader in this regard and has developed a set of instrumentation specific to this procedure. In my experience, this approach works well, and patients are comfortable after surgery in comparison with patients undergoing a more traditional transseptal technique. Many patients are quite comfortable being released to go home on the first postoperative day. This, of course, is with the understanding that the signs and symptoms of diabetes insipidus must be recognized outside of the acute care setting.

In my own practice, using this technique, I have found it very helpful to work in collaboration with a head and neck surgeon who is adept at endoscopic sinus surgery. Procedures performed alongside a head and neck colleague invariably led to improved exposures that I otherwise would not have been able to obtain without a great deal more experience operating endoscopically in the nasal passageways. Working in collaboration also has made the procedure a bit more efficient in our hands with the concept of one surgeon being a camera operator while the other surgeon operates, akin to the way general surgeons perform laparoscopic procedures. With one surgeon focusing on providing an optimal view at all times with the endoscope through one nostril, the operating surgeon can work through the opposite nasal passage without hindrance of the endoscope and without the added tasks of clearing the top of blood or debris or stopping to reposition the endoscope during the tumor removal. At any rate, the endoscopic technique, whether performed alone or in tandem, seems to work well for a growing number of neurosurgeons throughout the neurosurgical community. I believe that the technique has passed beyond the "gimmick" stage and, in some surgeons' hands, offers some attractive advantages.

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Englewood, Colorado

This is probably the best description of the endoscopic transsphenoidal surgical technique I have had an opportunity to read and review in a long time. The report is laced with a number of important anatomic details and surgical principles that are also salient to the execution of the standard transsphenoidal microsurgical technique. Among these, the use of sphenoid sinus ostia for entry into the sphenoid sinus, recognition of the location of the carotid tubercles and of the optic nerve canals along the posteroinferior and posterosuperior walls of the sphenoid sinus, respectively, the need to visualize the planum sphenoidale and the clivus, the dura opening technique, and the description of the sequence of removal of pituitary macroadenomas are all very reminiscent of the standard transsphenoidal microsurgical technique. The report is clear, cogent, and concise, with ample evidence of the authors' thorough understanding of the anatomy and familiarity with the subtleties of endoscopic and microsurgical techniques. The authors' many invaluable suggestions regarding how to avoid complications are a testimony to their experience with the procedures. The illustrations are splendidly vivid. This is a "must read" for all of those professing to be endoscopic pituitary surgeons. Unfortunately, the authors do not detail the results or complications of the technique to justify their statement that this technique is associated with a lesser incidence

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Cranial Base Reconstruction after Transsphenoidal Surgery with Bioabsorbable Implants: Technical Note

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OBJECTIVE: Reconstruction of the cranial base is often necessary after transsphenoidal surgery to prevent the occurrence of cerebrospinal fluid rhinorrhea and to maintain anatomic integrity. In most cases, sellar packing (fat, muscle, gelatin sponge) may be supported by bone or cartilage harvested at the time of surgery. The use of synthetic material, however, becomes desirable in cases in which an autograft is not available. Low-molecular-weight polylactide implants may serve as an effective alternative because they are immunologically inert, magnetic resonance imaging-compatible, and easily contoured to custom-fit a defect.

METHODS AND RESULTS: MacroSorb (MacroPore, San Diego, CA) absorbable plates are made from amorphous 70:30 poly (L-lactide-co-D,L-lactide) polymers. Implants are malleable at temperatures of 70°C and solidify at room or body temperature; plates are resorbed in 18 months.

CONCLUSION: Polylactide polymer implants are effective adjuncts in transsphenoidal surgery when cranial base reconstruction is necessary and when an endogenous osseous or cartilaginous graft is unavailable.
(Neurosurgery 48:232–234, 2001)

Key words: Bioabsorbable, Pituitary gland, Polylactide, Reconstruction, Sella turcica, Transsphenoidal microsurgery

When the intracranial cerebrospinal fluid (CSF) space is violated in transsphenoidal surgery, reconstruction of the floor of the sella turcica and frontal fossa is essential to prevent the occurrence of postoperative CSF rhinorrhea (9, 10, 12, 18) and iatrogenic empty sella syndrome (7, 13, 16). This reconstruction ordinarily is accomplished by using cartilage or bone harvested from the nasal septum to maintain the position of a sealant material—adipose tissue (12, 19) or muscle (5), sometimes supplemented with fibrin glue. Synthetic or allograft implantation may be necessary when local bone or cartilage is unavailable. Endoscopic transsphenoidal surgery, for example, usually does not expose the cartilaginous or bony septum (8). The use of synthetic graft material may particularly be indicated for patients with recurrent sellar masses who require a second transsphenoidal approach, wherein nasal cartilage or bone may not be available.

Plates made from a polylactide polymer (MacroPore, San Diego, CA) offer an effective alternative in this circumstance; this material is compatible with magnetic resonance imaging, easily contoured, and widely distributed in the commercial market. Implementation of this technology also has been tolerated well by patients who have undergone implantation to treat craniofacial disorders (3, 4, 15).

MATERIALS AND METHODS

MacroSorb

MacroSorb implants (*Figs. 1* and *2*) are made from amorphous 70:30 poly (L-lactide-co-D,L-lactide) polymer that becomes malleable at temperatures near 70°C and become rigid in a few seconds when allowed to cool. Once implanted in a patient, the polymer is hydrolyzed to lactic acid monomers by nonspecific hydrolytic scission during a period of 18 to 24 months (2, 17). Lactic acid is then incorporated into the tricarboxylic acid cycle and converted to carbon dioxide and water (6) as the plate is fully absorbed.

Implantation

In our transsphenoidal practice, when an intraoperative CSF leak occurs during tumor resection, abdominal fat is harvested and implanted in the cranial base defect. A single large portion of fat seems more effective than several smaller pieces in preventing the egress of CSF (5). The plate is trimmed by scissors to approximate the defect. It is then heated to 70°C and contoured to fit

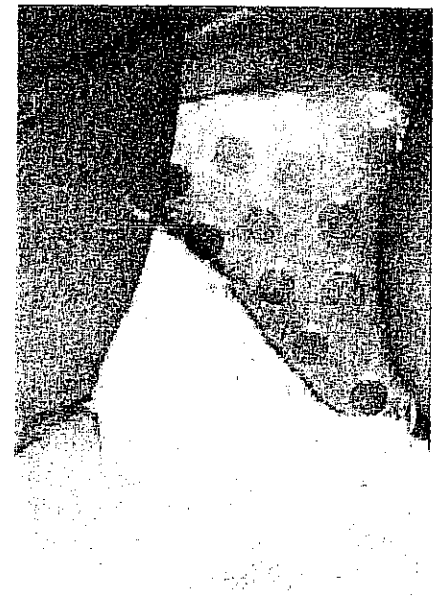

FIGURE 1. Polylactide polymer implant after trimming and contouring.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Michael J Ryan

Subject: 510(k) Number K062789/S1

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) ND

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

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

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

Predicate Product Code with class: 872.4760, II, SEY

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

Review: (Branch Chief) [signature] (Branch Code) FWB (Date) 2/27/07

Final Review: (Division Director) for [signature] (Date) 2/27/07

Revised:4/2/03

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REVISED: 2.26.2007

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K062789/S1

Reviewer: Michael J. Ryan
Division/Branch: DAGID/DEDB
Device Name: *Synthes USA Rapid Resorbable Fixation System*
Product To Which Compared (510(K) Number If Known): See Memo

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

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

* See attached review memorandum for relevant explanations, intended use, and device description.

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U.S. Department of Health and Human Services
Food and Drug Administration

REVIEW MEMORANDUM

Date: February 26, 2007

From: Michael J. Ryan
Biomedical Engineer
DAGID, HFZ-480

To: The record

Subject: *Synthes USA Rapid Resorbable Fixation System* (K062789/S1)
Synthes USA
West Chester, Pennsylvania

Contact: Jeffrey Dow
484-356-9720

RECOMMENDATION: Substantially Equivalent (SE)

IFU: For use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations. In addition, resorbable meshes, sheets, screws, and tacks may be used in non-load bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts, (autograft or allograft), or bone graft substitutes in reconstruction of the craniofacial or mandibular areas. These devices are not intended for use in load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. The Synthes Rapid Resorbable System is not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

I. BACKGROUND

Synthes USA have submitted a Pre-Market Notification to introduce into U.S. interstate commerce a bone plate system, *Synthes USA Rapid Resorbable Fixation System*. This device is regulated as a "bone plate," a Class II medical device regulated under 21 CFR 872.4760, product code JEY. The predicate devices used in the review of this 510(k) are the *LactoSorb Trauma Plating System* (K971870) and the *Synthes Rapid Resorbable Fixation System* (K050204/K030069).

II. CORRESPONDENCE/APPLICATION CHANGES

- **November 20, 2006: TH** – This application was put on hold. Information on the indications for use, the resorption time of the device material, and clarifications regarding the engineering rationales provided were requested.
- **January 5, 2007: Teleconference** – The sponsor and I discussed their proposed answers to the questions posed in the TH fax of November 20th.
- **January 12: AI Request** – Additional information regarding the indications for use was requested.
- **February 5: S1** – Supplement 1 was received by the DMC.

III. REVIEWER'S ANALYSIS

This submission seeks clearance for a resorbable bone plate system for use in fracture repair and reconstructive procedures of the craniofacial region. This system combines devices previously cleared by the sponsor, Synthes, adds some slightly modified plate designs, and revises the indications for use to explicitly include pediatric populations.

Design – This 510(k) submits a system of several different bone plate, mesh, screw and tack designs with several minor device modifications and expanded indications for use. The device modifications included in this submission are all addressed with engineering rationales, as discussed below. The modifications include a groove in the top of some plates to offer the surgeon tactile feedback, a more flexible "pinwheel" mesh design, and additional scalloped plate designs. All devices are made from 85:15 poly-L-lactide-co-glycolide, as were the previously cleared Synthes plate and screw. The designs are similar enough in volume that the resorption timeframe should be within the limits of the previously cleared devices. The new designs are also similar enough to the previously cleared plates, meshes, screws, and tacks that no new risks are presented.

Indications for Use – The indications for use statement is nearly identical to that of the sponsor's previously cleared K030069, with the exception that the current 510(k) adds pediatric populations to the indications. Several 510(k)s have cleared similar reconstructive plates for use in pediatric populations. One of the first seems to be K971870, for the *LactoSorb Trauma Plating System*, which is indicatied for midface and craniofacial procedures and is also made of poly-L-co-glycolide. In the review of this submission, Dr. Mary McGrath, a member of the Plastic and Reconstructive Surgery Panel, was consulted. Dr. McGrath found the new indications including pediatric populations equivalent to the predicate indications. In addition, a limited literature search on Medline turned up no adverse

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information about using resorbable reconstructive systems in pediatric populations, although I was unable to find information on populations under 6 years of age. It seems that none of the previous submissions that indicate resorbable plates for pediatric populations limited the population in their indications for use statements or instructions for use. However, Synthes has revised their instructions for use to state that their devices are not intended for newborns. Considering all of this information, the sponsor's new indications for use statement is equivalent to predicate indications for use statements, such as that of K971870.

Biocompatibility – These devices are made from 85:15 poly-L-lactide-co-glycolide. The previously cleared Synthes resorbable bone plate systems were made from the same material and used in a similar fashion. Therefore, there are no biocompatibility concerns.

Bench testing – The sponsor provided four engineering rationales to demonstrate that the modified devices of this submission are similar to those cleared in K030069. The engineering rationale in section 4(a) provides results from a bending test that shows the average strength of modified plates to be almost 2 N higher than the average strength of predicate plates. The engineering rationale in section 4(b) provides volume calculations of new meshes compared to predicate meshes, and shows that the volume of the new meshes are within the ranges of predicate meshes. This shows that the resorption timeframe should be similar. Since the thickness of the new mesh is greater than predicate meshes, mechanical strength should also be similar. The engineering rationales in sections 4(c) and 4(d) provide no calculations or tests, and instead point out that since the dimensions of the modified plates discussed in those sections are within dimensions of predicates, no new risks are presented.

Sterilization – The sponsor has submitted a proper sterilization validation statement for these devices. They are provided gamma sterilized. Validation will be done according to ISO 11137.

Labeling – The labeling is clear, descriptive, and includes all applicable warnings.

IV. RECOMMENDATION

The information submitted demonstrates that the *Synthes USA Rapid Resorbable Fixation System* and legally marketed devices have similar designs, indications for use, and there are no new technological characteristics capable of affecting safety and effectiveness. The *Synthes USA Rapid Resorbable Fixation System* is substantially equivalent (SE) to predicate bone plate systems.

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Primary Reviewer:

Michael J. Ryan
Biomedical Engineer

Branch Chief:

Susan Runner, D.D.S., MA
Branch Chief, Dental Devices Branch

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

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

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

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

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

5. Describe the new technological characteristics:

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

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

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

10. Explain what performance data is needed:

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Michael J Ryan

Subject: 510(k) Number K062789

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

☐ Refused to accept.
☑ Requires additional information (other than refuse to accept). Telephone Hold
☐ Is substantially equivalent to marketed devices.
☐ NOT substantially equivalent to marketed devices.
☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☐ NO
Is this device subject to the Tracking Regulation?	☐ YES	☐ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☐ NO
Is this a prescription device?	☐ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☐ NO
Special 510(k)?	☐ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☐ NO

Truthful and Accurate Statement ☐ Requested ☐ Enclosed
☐ A 510(k) summary OR ☐ A 510(k) statement
☐ The required certification and summary for class III devices
☐ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) _____

Animal Tissue Source ☐ YES ☐ NO Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 da

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

Review: Susan Runner (Branch Chief) DEPH (Branch Code) 11/20/06 (Date)

Final Review: Susan Runner (Division Director) 11/20/06 (Date)

Revised:4/2/03

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U.S. Department of Health and Human Services
Food and Drug Administration

REVIEW MEMORANDUM

Date: November 17, 2006

From: Michael J. Ryan
Biomedical Engineer
DAGID, HFZ-480

To: The record

Subject: *Synthes USA Rapid Resorbable Fixation System* (K062789)
Synthes USA
West Chester, Pennsylvania

Contact: Jeffrey Dow
484-356-9720

RECOMMENDATION: Telephone Hold (TH)

IFU: Intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations. In addition, resorbable meshes, sheets, screws and tacks may be used in non-load bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts, (autograft or allograft), or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.
These devices are not intended for use in load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. The Synthes Rapid Resorbable System is not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

I. BACKGROUND

Synthes USA, of West Chester, Pennsylvania, has submitted a Pre-Market Notification to introduce into U.S. interstate commerce a bone plate system, *Synthes USA Rapid Resorbable Fixation System.* This device is regulated as a "bone plate," a Class II medical device regulated under 21 CFR 872.4760, product code JEY.

II. CORRESPONDENCE/APPLICATION CHANGES

- **No changes have been made.**

III. REVIEWER'S ANALYSIS

The current submission submits a dental bone plate system, complete with fixation screws and tacks. The entire system is made of resorbable poly-L-lactide-co-glycolide. The system submits several new plates, and seeks to add pediatric use to the indications statement.

The new indications for use statement is compared to that of a predicate device cleared under K971870, Biomet, Inc.'s *LactoSorb Trauma Plating System.* These devices are very similar, with the only major difference being the different plate options. Under that review, it was determined that pediatric use was similar to that of adult use, and that in fact, pediatric use was implied in the general indications already granted to that device. Similar general indications have been granted to the current device as well. However, the indications of the current device are slightly different from those of the predicate, and no justification has been provided. Synthes should justify the differences, or revise the indications requested.

In addition, other issues are apparent from review of this 510(k). Please see the attached telephone hold facsimile for details.

IV. RECOMMENDATION

Additional information is required to find this submission substantially equivalent to predicate devices. Such information should be requested, and the document should be placed on telephone hold (TH).

Primary Reviewer:

Michael J. Ryan
Biomedical Engineer

Branch Chief:

Susan Runner, D.D.S., MA
Branch Chief, Dental Devices Branch

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DHHS/Food & Drug Administration
Center for Devices and Radiological Health
9200 Corporate Boulevard, HFZ-401
Rockville, MD 20850
Phone: 240.276.3717
Fax: 240.276.3789
Mail: michael.ryan@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
FACSIMILE*

To:	Mr. Jeffrey Dow	**From:**	Michael J. Ryan MR
Fax:	484-356-9682	**Pages:**	1 (inc. cover)
Phone:	484-356-9720	**Date:**	11/17/2006
Re:	510(k) for **Synthes USA Rapid Resorbable Fixation System (K062789)**	**CC:**	

☑ **Urgent** ☑ **For Review** ☐ **Please Comment** ☑ **Please Reply** ☑ **Please Recycle**

Dear Mr. Dow,

I have reviewed the 510(K) submission, **Synthes USA Rapid Resorbable Fixation System (K062789)**, and I have found the following issues must be resolved before review can continue.

1. The indications for use statement provided for this submission includes indications that the predicate devices were not cleared for, such as use in mandibular areas. No data has been provided to justify this additional indication. Please either remove these additional indications or provide justification for their inclusion.

2. The attached list of products that are covered by this 510(k) should refer to device drawings. Please revise the chart to show which 510(k) a drawing would be located in. As for the devices for which no 510(k) was submitted, please provide drawings here for our records.

3. Please provide information on the resorption times of these devices, including the new designs. This information should also be included in the instructions for use, since different devices may have different resorption timelines.

4. Page 53 of the submission, or page 3 of the August 29 engineering rationale, provides a chart indicating strength values for plates. Please clarify which plate is the new design, and which plate is the previously cleared design.

5. It is not clear from some of the engineering rationale reports exactly what design modifications were made. Please provide a summary report that explains the modifications made to the plates and meshes and matches those modifications with the appropriate engineering report.

November 17, 2006

Please fax or email your response to **Mike Ryan** (**Fax: 240-276-3789; Email: michael.ryan@fda.hhs.gov**) and follow up with **a hard copy** to the **Document Mail Center** at the address above. **Your document will be placed on hold.** Review of your application will resume once the above information has been submitted. Please call me at **240-276-3717** if you have any questions.

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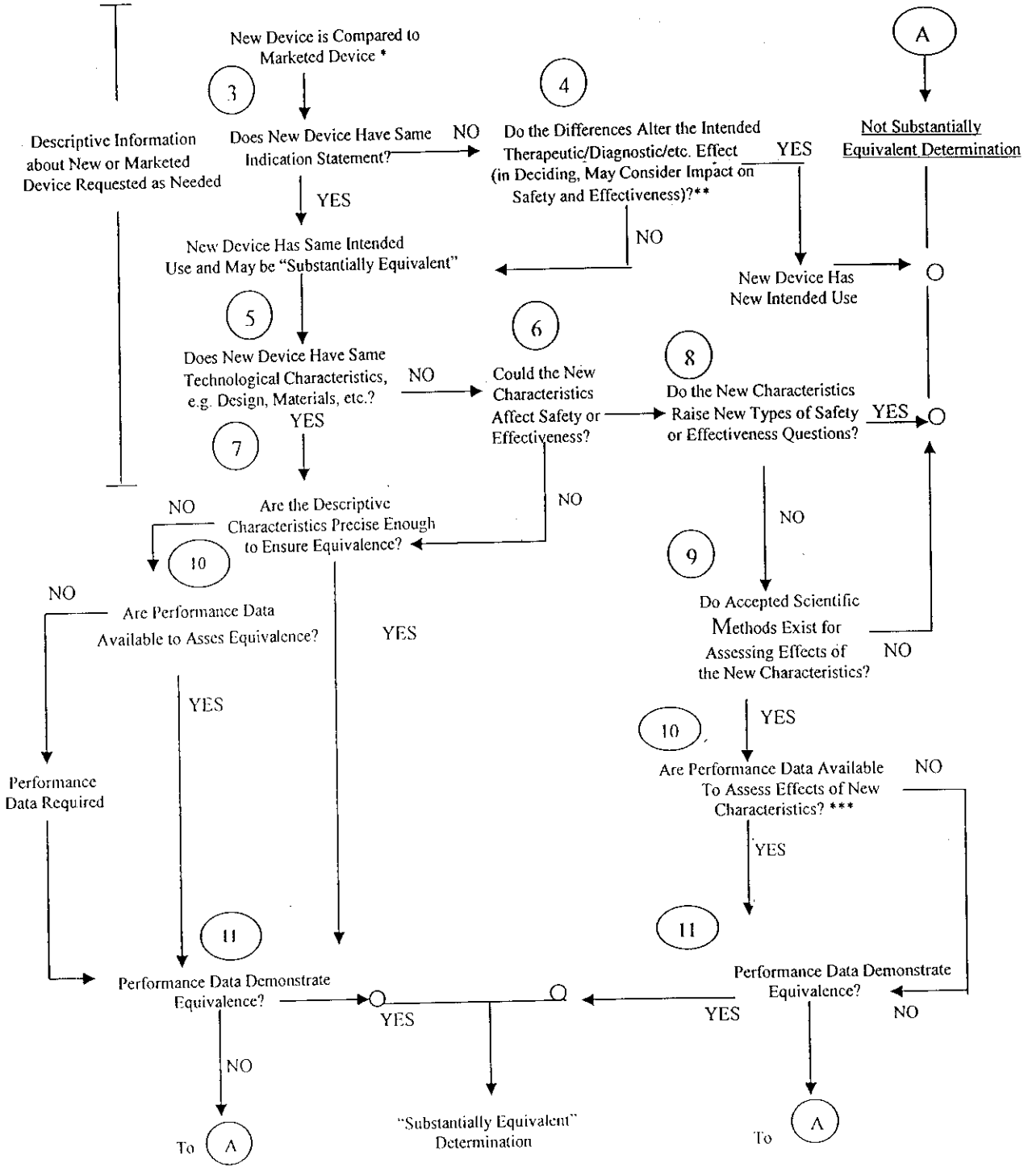
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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

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

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

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Internal Administrative Form

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

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

510(k) Number: K062789

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

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

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

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

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

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

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

** - Required for Class III devices, only.

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

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

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

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

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard**, which is posted with the 510(k) boilers on the **H drive.**]		

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

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

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

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

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

Passed Screening ✓ Yes ____ No

Reviewer:_____

Concurrence by Review Branch:_____

Date: SEP 2 5 2006

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

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

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

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

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

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

5. Describe the new technological characteristics:

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

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

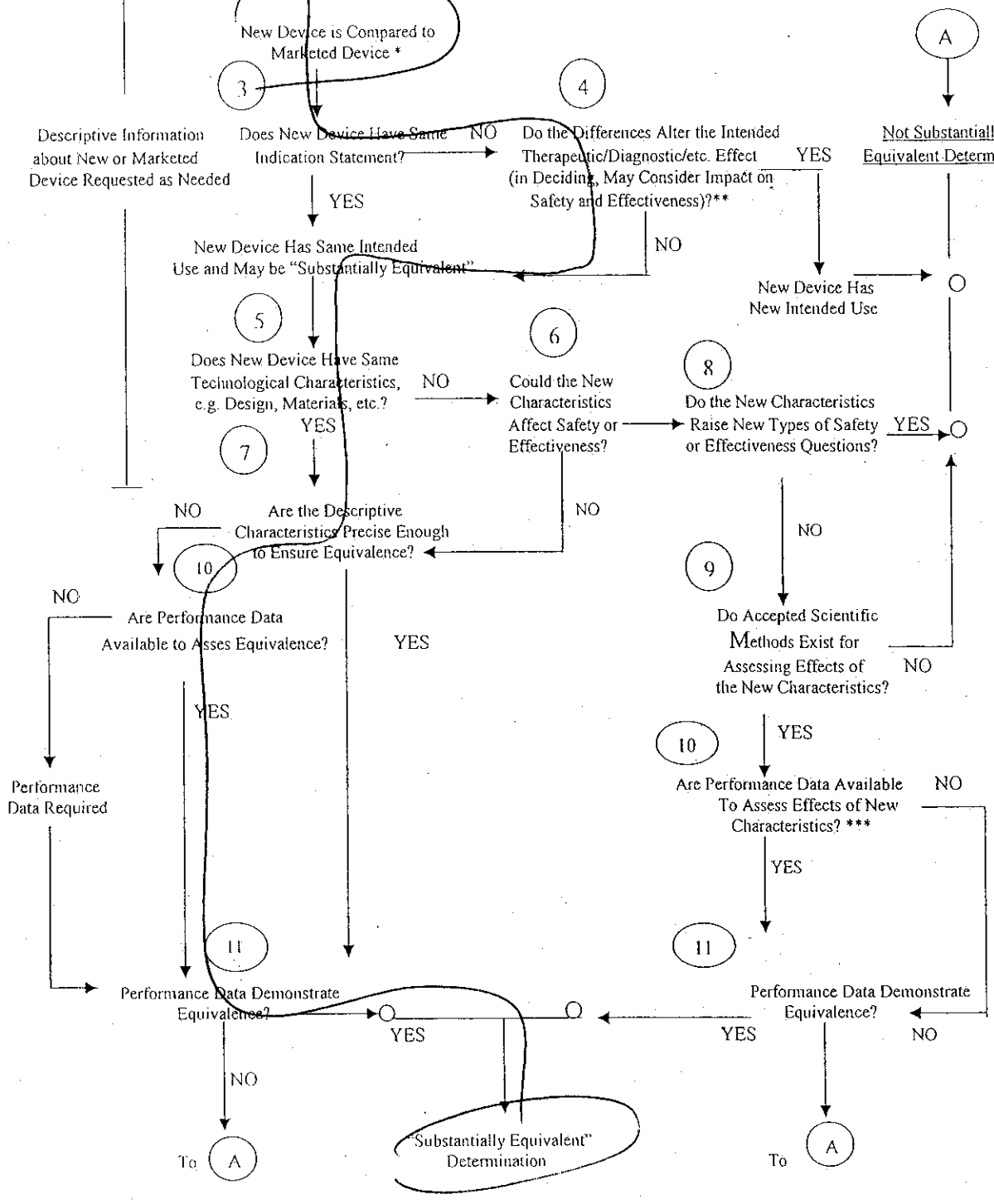
9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

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



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

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

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

5

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40
9200 Corporate Blvd.
Rockville, Maryland 20850

February 05, 2007

SYNTHES (USA)
1230 WILSON DRIVE
WEST CHESTER, PA 19380
ATTN: JEFFREY DOW

510(k) Number: K062789
Product: SYNTHES (USA)
RAPID RESORBABLE
FIXATION SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

SYNTHES®

K062789/S1

February 2, 2007

510(k) Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

K-18

Attn. : Michael J. Ryan

Ré: K062789, Synthes (USA) Rapid Resorbable Fixation System

Dear Sir/Madam:

On September 12, 2006 Synthes (USA) submitted its 510(k) application for the above system. On November 21, 2006, Mr. Michael Ryan, by facsimile, attached, advised Synthes that he had five issues that must be resolved before his review could continue. On January 5, 2007, following a telephone conference between Mr. Ryan and Synthes representatives (including the undersigned), Synthes requested an extension of time to February 5 to respond to these issues. This request was granted on January 12. Subsequently, on January 24, 2007, by phone confirmed by an e-mail of the same date, attached, Mr. Ryan asked an additional two questions which required Synthes' additional responses. This letter is Synthes' complete response to all of the issues and questions raised by Mr. Ryan.

For convenience, each issue or question raised by Mr. Ryan is reproduced here in full in boldface type, and is followed immediately thereafter by Synthes' complete response to it. Where the response refers to information contained in separate documents, those documents are attached and identified by numbered tabs. In addition to the two copies submitted herewith, a separate desk copy has been simultaneously sent directly to Mr. Ryan.

Items from facsimile of November 21, 2006.

1. **"The indications for use statement provided for this submission includes indications that the predicate devices were not cleared for, such as use in mandibular areas. No data has been provided to justify this additional indication. Please either remove these additional indications or provide justification for their inclusion."**

On April 8, 2003 FDA notified Synthes that it had found its 510(k) K030069 for Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation system to be substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976. In this notification FDA cleared the following excerpt of the indication:

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> "In addition, Resorbable Meshes, Sheets and Screws may be used in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or *mandibular* areas" [emphasis added].

A copy of the clearance letter for K030069, and the Indication for Use Statement appended thereto are attached to this response as **Tab #1**. K030069 was cited by Synthes as a predicate device in the present 510(k), K062789 (*see, e.g., K062789, p.6).* The proposed indication for use in K062789 repeats verbatim the quoted indication for use cleared by FDA in K030069 (except for the addition in K062789 of the word "tacks" in the third line of that indication, which is irrelevant to the issue raised by Mr. Ryan).

Synthes therefore respectfully submits that predicate devices have been cleared for use in mandibular areas.

> **"2.The attached list of products that are covered by this 510(k) should refer to device drawings. Please revise the chart to show which 510(k) a drawing would be located in. As for the devices for which no 510(k) was submitted, please provide drawings here for our records."**

We respectfully suggest that the chart does not require revision. The drawings requested are supplied at **Tab #2**.

The device drawings to which Mr. Ryan's query applies are summarized in the table at pages 16-21 (K062789, Attachment 1). There are two different categories to which the table applies, those drawings designated in "normal face" type, and those designated in boldface type.

The drawings in normal face are those in which the drawings to which they refer are reproduced in K030069, at Attachment 5. The drawings shown in boldface are drawings of products not extant on the date of submission of K030069, but which were subsequently drawn, reviewed, validated and adopted. These are the drawings that are attached at Tab #2, in the order in which they appear in the chart in K062789. Thus, the chart in K0627890 does show the 510(k) in which each drawing would be located[1].

> **"3. Please provide information on the resorption times of these devices, including the new designs. This information should also be included in the instructions for use, since different devices may have different resorption timelines."**

Information on the resorption times for Synthes Resorbable Fixation System was contained at Attachment 10 of Synthes predicate device cleared in 510(k) K030069. It is

[1] N.B. There is a slight difference in the order in which subgroups of the preexisting (normal face type) drawings are presented in K030069 and K062789, but the drawings themselves and their reference numbers are identical in both 510(k)s.

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reproduced here at Tab#3. That Polymer Comparison Analysis report found that the resorption times of both Synthes' System, and the predicate device to that System, Walter Lorenz Surgical LactoSorb® Trauma Plating System, would resorb in approximately the same time, 12 months.

All plates listed in K062789 lie within the size ranges or volumes cleared by the previously approved 510(k) K030069. The instructions for use in the present application currently claim that, "The material resorbs in approximately 12 months." (K062789, p.9, top). Cleared competitive products have the same information on resorption times. Examples of the directions for use of these cleared competitive products are similarly included at **Tab #3**.

If size and shape are comparable, and if the material used is the same, there is no significant difference in the resorption time between the devices described in the original submission and those cited in the cleared predicate devices. Thus, there should be no need for additional information in the instructions for use.

> **"4. Page 53 of the submission, or page 3 of the August 29 engineering rationale, provides a chart indicating strength values for plates. Please clarify which plate is the new design, and which plate is the previously cleared design."**

The headings to the chart on page 3 of the August 29 engineering rationale (submission Attachment 4(a), p.53) have been modified as requested. **Tab #4** contains a revision of the whole of Attachment 4(a).

At the bottom of page 3 of Tab #4, the headings to the chart on page 3 have been changed as follows:

- **Columns 2 and 4**, currently labeled "Average Strength from 510k Testing" have added the phrase "(previously cleared scalloped style)" to reflect a reference to the predicate device.

- **Columns 3 and 5**, currently labeled "Average Strength from Product Quality Testing" have added the phrase "(new straight side style)" to reflect a reference to the device covered by the current submission.

> **"5. It is not clear from some of the engineering rationale reports exactly what design modifications were made. Please provide a summary report that explains the modifications made to the plates and meshes and matches those modifications with the appropriate engineering reports."**

We have further modified the information in Attachment 4(a) of the present submission to add drawings intended to aid the reviewer in better understanding the nature of the modifications made to the plates and meshes. Attachment 4(a) at Tab #4 now matches those modifications to the engineering reports in Attachment 4(a) from the predicate to

the current devices. Beginning on page 4 of Tab #4, labeled "Attachment A" through "Attachment" E, are drawings of the changes to each of the subset of devices covered by the chart in Attachment 4(a) to which those drawings refer. In each instance, the predicate device drawing is labeled "Example Original Style", and the new device is labeled "Example New Style".

Tab #5 similarly contains an addendum to the Burr Hole Cover Rationale dated 13 August, 2003 included in K062789 at Attachment 4(c) that similarly shows the "Original Style" predicate device and its modified "New Style" device. Synthes believes that all other drawings accompanying engineering rationales are appropriately labeled in the current submission.

Items from the e-mail of January 24, 2007.

> **"1. Is this device indicated for a specific age-range of pediatric patients? As it is currently written, the indications simply mention pediatric populations. Please justify the choice of either a specific age-range or the general pediatric population. You may wish to refer to predicate devices with pediatric indications and any available literature on pediatric use of these devices."**

Synthes does intend that its Rapid Resorbable System be used in a specific age-range of patients. We define pediatric patients as age 1 month through 21 years. This is consistent with the FDA pediatric subpopulations of infant, child, and adolescent defined in Table 1of CDRH and CBER Guidance "Premarket Assessment of Pediatric Medical Devices," July 24, 2004, p. 4.

Use of resorbable implants in these pediatric populations minimizes clinical concerns with metallic plates and screws, including the risks of growth restriction and transcranial migration of hardware. The available literature reproduced at Attachment 5 of the K062789 was included to support the use of these devices in pediatric patients.

Synthes disclaims any intent to indicate its Rapid Resorbable System for use in newborns (neonates) from birth to 1 month of age, and will amend its Directions for Use in Attachment 2 of the original submission to add the following to the section on Warnings and Precautions:

> "These devices are not intended for use in newborn (neonate) children from birth to 1 month of age."

> **2. "Please explain whether the use of these plates in pediatric patients necessitates any additional labeling. Please justify your answer, and again, it may be useful to reference predicate devices with pediatric indications and any available literature."**

Synthes will amend its Directions for Use in the original submission to include a warning that the devices are not intended for newborns (neonates). In all other respects its

suggested labeling is consistent with that cleared by FDA in competitive devices. As requested, Synthes has included at **Tab #3** references to predicate devices and their respective Directions for Use.

Synthes believes that these responses are complete responses to the issues raised by Mr. Ryan in his facsimile and e-mail. If he or any other reviewer has additional comments or questions about these responses or the submission, please telephone me at 484 356 9720, or e-mail me at dow.jeff@synthes.com.

Sincerely,

Jeffrey L. Dow, JD
Director, R/A & C/A
Synthes Biomaterials

Attachments

DHHS/Food & Drug Administration
Center for Devices and Radiological Health
9200 Corporate Boulevard, HFZ-401
Rockville, MD 20850
Phone: 240.276.3717
Fax: 240.276.3789
Email: michael.ryan@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration

FACSIMILE*

To:	Mr. Jeffrey Dow	**From:**	Michael J. Ryan
Fax:	484-356-9682	**Pages:**	1 (inc. cover)
Phone:	484-356-9720	**Date:**	11/21/2006
Re:	510(k) for **Synthes USA Rapid Resorbable Fixation System (K062789)**	**CC:**	

☑ **Urgent** ☑ **For Review** ☐ **Please Comment** ☑ **Please Reply** ☑ **Please Recycle**

Dear Mr. Dow,

I have reviewed the 510(K) submission, **Synthes USA Rapid Resorbable Fixation System (K062789)**, and I have found the following issues must be resolved before review can continue.

1. The indications for use statement provided for this submission includes indications that the predicate devices were not cleared for, such as use in mandibular areas. No data has been provided to justify this additional indication. Please either remove these additional indications or provide justification for their inclusion.

2. The attached list of products that are covered by this 510(k) should refer to device drawings. Please revise the chart to show which 510(k) a drawing would be located in. As for the devices for which no 510(k) was submitted, please provide drawings here for our records.

3. Please provide information on the resorption times of these devices, including the new designs. This information should also be included in the instructions for use, since different devices may have different resorption timelines.

4. Page 53 of the submission, or page 3 of the August 29 engineering rationale, provides a chart indicating strength values for plates. Please clarify which plate is the new design, and which plate is the previously cleared design.

5. It is not clear from some of the engineering rationale reports exactly what design modifications were made. Please provide a summary report that explains the modifications made to the plates and meshes and matches those modifications with the appropriate engineering report.

Dow, Jeff

From: Ryan, Michael J [michael.ryan@fda.hhs.gov]

Sent: Wednesday, January 24, 2007 12:00 PM

To: Dow, Jeff

Subject: RE: K062789/Synthes USA Rapid Resorbable Fixation System

Dear Jeff,

We spoke earlier today regarding the pediatric indications for your device. Please address the following two questions:

1. Is this device indicated for a specific age-range of pediatric patients? As it is currently written, the indications simply mention pediatric populations. Please justify the choice of either a specific age-range or the general pediatric population. You may wish to refer to predicate devices with pediatric indications and any available literature on pediatric use of these devices.
2. Please explain whether the use of these plates in pediatric patients necessitates any additional labeling. Please justify your answer, and again, it may be useful to reference predicate devices with pediatric indications and any available literature.

Thanks for your help, Jeff. Please let me know if you have any questions.

Regards,
Mike Ryan

Michael J Ryan
Biomedical Engineer
Food & Drug Administration
Dental Devices Branch
Phone: 240.276.3717
Fax: 240.276.3789

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 8 2003

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K030069
Trade/Device Name: Sythes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: January 6, 2003
Received: January 8, 2003

Dear Ms. Smith:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use Statement

510(k) Number (if known): K030069

DEVICE NAME: Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System

INDICATIONS: Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System devices (Plates, Meshes, Sheets, and Screws) are intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton. In addition, Resorbable Meshes, Sheets and Screws may be used in non-load bearing applications for maintaining the relative position of and/or containing bony fragments, bone grafts (autograft or allograft) or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

CONTRAINDICATIONS: These devices are not intended for use in full load bearing applications, such as the mandible, unless used in conjunction with traditional rigid fixation. Synthes Poly (L-Lactide-co-Glycolide) Resorbable Fixation System devices are not intended for areas with active or latent infection or for patient conditions including limited blood supply or insufficient quantity or quality of bone. These devices are not intended for use in the spine.

(PLEASE NO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-the-Counter Use _____

Ken Mulay for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K030069

Synthes (USA)
Premarket Notification 510(k)
PLLA/PGA Resorbable Fixation System

CONFIDENTIAL

25

(b)(4) Schematic drawing

(b)(4) Schematic drawing

(b)(4) Schematic drawing

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(b)(4) Schematic drawing

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(b)(4) Schematic drawing

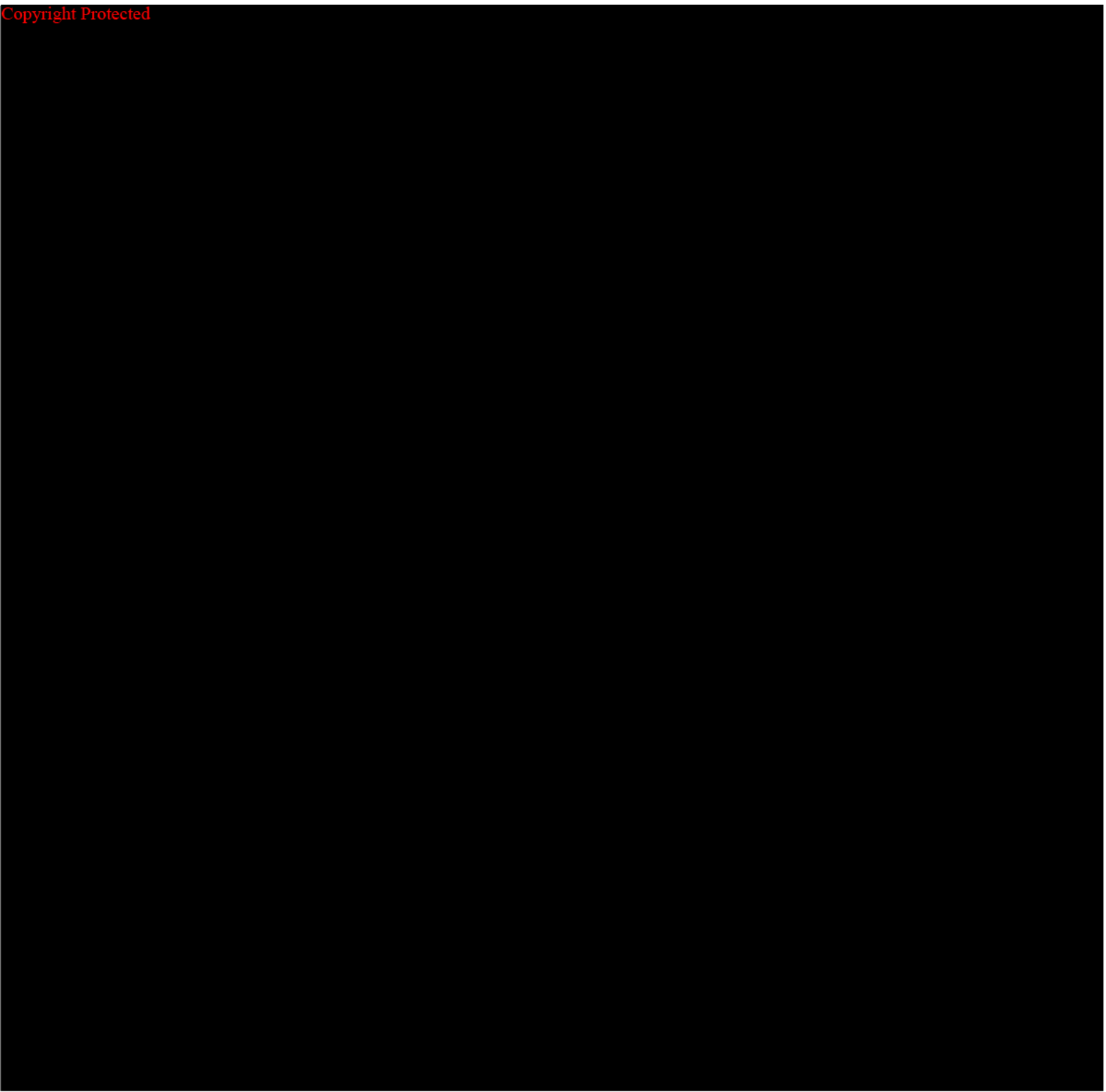
(b)(4) Schematic drawing

SYNTHES

POLYMER COMPARISON ANALYSIS

Synthes 85:15 Poly(L-Lactide-co-Glycolide)
vs.
LactoSorb® 82:18 Poly(L-Lactide-co-Glycolide)

Written by:
Jim Dwyer, Synthes Process Development Engineer



SYNTHES

Inherent Viscosity

(b)(4)

[redacted]

SYNTHES

(b)(4)

[redacted]

Distributor:
Walter Lorenz Surgical, Inc. **1-50-1050**
1520 Tradeport Drive
P.O. Box 18009
Jacksonville, Florida 32229-8009 USA

Date: 08/10/98

LACTOSORB® TRAUMA PLATING SYSTEM

ATTENTION OPERATING SURGEON

DESCRIPTION

The Lactosorb® Trauma Plating System consists of resorbable fixation devices (plates, meshes, screws, and rivets). The system is used in trauma and reconstructive surgical procedure in the midface and craniofacial skeleton.

The plates/screws are made of a resorbable copolymer, a 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

A. General Indications: trauma procedures of the midface or craniofacial skeleton

Specific Indications:

1. comminuted fractures of the naso-ethmoidal and intraorbital area.
2. comminuted fractures of the frontal sinus wall.
3. pediatric midface or craniofacial trauma
4. LeFort (I,II,III) fractures
5. orbital floor fractures
6. fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones.
7. trauma of the craniofacial skeleton, including frontal, parietal, temporal, sphenoid, and occipital bones

B. General Indication: reconstructive procedures of the midface or craniofacial skeleton

Specific Indication:

1. infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.
2. LeFort (I,II,IIII) osteotomies
3. tumor reconstruction in midface or craniofacial procedures
4. bone graft procedures in the midface or craniofacial skeleton
5. pediatric reconstructive procedures
6. reconstructive procedures of the craniofacial skeleton including, frontal, parietal, temporal, sphenoid, and occipital bones
7. craniotomy flap fixation

CONTRAINDICATIONS

1. Active infection.
2. Patient conditions including, blood supply limitations, insufficient quantity or quality of bone stock or latent infection.
3. DO NOT USE in the mandible.
4. DO NOT USE in full load bearing procedures.
5. DO NOT USE in the temporomandibular joint (TMJ).

WARNINGS

1. Improper selection, placement, positioning, and fixation of the implant can cause a subsequent undesirable result. The surgeon is to be familiar with the devices, the method of application and the surgical procedure prior to performing surgery.
2. These resorbable devices provide fixation and are not intended to replace normal healthy bone or withstand stress of full weight bearing.
3. These devices are resorbable and do not provide permanent fixation. DO NOT USE in procedures where a permanent implant is needed.
4. The plates/meshes can be heated and shaped as desired up to and including three times using the Lactosorb® Heat Pack. Use of any other method to heat the plates is not recommended. Screws are not to be heated or reshaped by any means.
5. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure of the plates and/or screws which could require additional surgery and device removal.
6. Discard and DO NOT USE previously opened or damaged devices. Use only devices that are packaged in unopened or undamaged containers.
7. DO NOT USE if there is loss of sterility of the device.

PRECAUTIONS

1. The patient is to be warned that the device can break or loosen as a result of stress, excessive activity or load bearing.
2. 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 instructions can cause failure of the implant and the treatment.
3. Do not use Lactosorb implants with resorbable implants made by other manufactures due to the probability of incompatible fits, size and rate of resorption.
4. Instruments are available to aid in the accurate implantation of Lactosorb fixation devices. Intraoperative fracture of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments are only to be used for their intended purpose. All instruments are to be regularly inspected for wear and disfigurement.

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.

STERILITY

The Lactosorb implants are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize.

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

Manufacturer:
Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46580

Authorized Representative:
Biomet Merck
Waterton Industrial Estates
Bridgend, South Wales
321CF 3AX, U.K.

CE 0086

ENGLISH

DESCRIPTION
The Stryker Leibinger DeltaSystem consists of resorbable bone fixation plates, meshes and screws made from a terpolymer of polylactic and polyglycolic acids. The terpolymer degrades and resorbs in-vivo by hydrolysis into lactic and glycolic acids which are then metabolized by the body.

Sterile only if foil package is unopened and undamaged. Single patient use only. Do not resterilize or reuse.

Prior to use, this device should be inspected for damage. Do not use if damage is apparent.

Read and understand these instructions prior to use. The *DeltaSystem* must be used by persons familiar with surgical procedures.

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

INDICATIONS FOR USE
The Stryker Leibinger DeltaSystem is intended for use in the fixation of bones of the craniofacial and midfacial skeleton affected by trauma or for reconstruction. The system can be used in both adult and pediatric patients.

CONTRAINDICATIONS
This device is not recommended for use under the following circumstance:
- Active infection
- Patient conditions including blood supply limitations, insufficient quantity or quality of bone or latent infection
- DO NOT use in the mandible or temporal mandibular joint
- DO NOT use in full load bearing procedures

WARNINGS
- Improper selection, placement, positioning, and fixation of the implant can cause a subsequent undesirable result.
- The surgeon must be familiar with the devices, the method of application and the surgical procedure prior to performing surgery. Misuse may cause injury to the patient.
- These resorbable devices provide fixation and are not intended to replace normal healthy bone or withstand stress of full load bearing.
- These devices are resorbable and do not provide permanent fixation. Do not use in procedures where a permanent implant is needed.
- The plates can be heated and contoured using ONLY the water bath unit provided by Stryker Leibinger. Screws are not to be heated or reshaped by any means.

- Limit heating plates and meshes to a maximum of three (3) times at 15 seconds each time they are placed in the water bath. Discard implants that have exceeded these limits.
- The devices can break or be damaged due to excessive activity, trauma or load bearing. This could lead to failure of the plates and/or screws which could require additional surgery and device removal.
- Discard and DO NOT use previously opened or damaged devices. Use only devices that are packaged in unopened or undamaged foil pouches.
- Do not use if there is loss of steriliy of the device.
- Do not use Stryker Leibinger implants with resorbable implants made by other manufacturers.
- Discard device if safety dot has turned black. A black dot indicates that the device has reached 120°F (49°C) and is potentially damaged.

POSSIBLE ADVERSE EFFECTS
- Infection can lead to failure of the procedure.
- Neurovascular injuries can occur due to surgical trauma.
- Bending, fracture, loosening, rubbing and migration of the devices can occur as a result of excessive activity, trauma or load bearing.
- Implantation of foreign materials can result in an inflammatory response or allergic reaction.

STERILITY
DeltaSystem resorbable implants are sterilized by exposure to Ethylene Oxide (ETO) gas. Do not resterilize.

SYMBOL DEFINITION

Discard device when dot is black.
A black dot indicates that the 120°F [49°C] storage temperature limit has been exceeded and therefore the device may be damaged.

ESPAÑOL

DESCRIPCIÓN
El DeltaSystem de Stryker Leibinger consiste de placas, mallas y tornillos reabsorbibles de fijación ósea de un terpolímero de ácidos poliláctico y poliglicólico. El terpolímero se degrada y reabsorbe in-vivo por hidrólisis en ácidos poliláctico y poliglicólico que son luego metabolizados por el cuerpo.

Estéril solamente si no se ha abierto o dañado el paquete metálico. Para usar solamente en un único paciente. No se debe volver a esterilizar ni utilizar.

Antes de usar, se debe inspeccionar este dispositivo por posibles daños. No usar si hay daños aparentes.

Leer y entender estas instrucciones antes de usar. El *DeltaSystem* debe ser utilizado por personas familiarizadas con procesos quirúrgicos.

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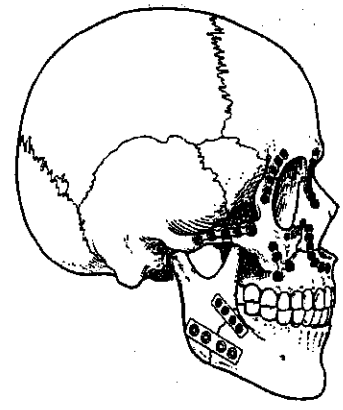
Polymer Development

29 August 2006



To: DHF M01-029 Rapid Resorbable System

Cc: Regulatory Department

From: Ralph Zwirnmann 23JAN07

Re: Modification to Rapid Resorbable Plates

Rationale regarding changes to plates:

- The following changes were incorporated in 2003.
- A bevel was added to the outer edge and a shallow groove to the center of the top surface in order to give the surgeon tactile feedback indicating the top side of the plate. The addition of these features required that the plate become 1mm wider and, thereby, 1mm longer in order to maintain similar strength. The plate thickness remained the same.
  (For an example of this change see Attachment A)

Old Part Number	AO Part Number	Description
M01029_1002	851.002	1.5mm Straight Plate, 2 holes
M01029_1004	851.004	1.5mm Straight Plate, 4 holes
M01029_2002	852.002	2.0mm Straight Plate, 2 holes
M01029_2004	852.004	2.0mm Straight Plate, 4 holes

- The following plates were updated from scalloped sides to straight sides in order to incorporate a bevel on the outer edge and a shallow groove in the center of the top surface in order to give the surgeon tactile feedback indicating the top side of the plate. The addition of these features required that the plate become 1mm wider and, thereby, 1mm longer in order to maintain similar strength. The plate thickness remained the same. One further addition is a series of narrow slots in-between each screw hole. When forming the plate becomes necessary, these slots enable the plate to bend in-between rather than through the screws holes.
  (For an example of this change see Attachment B)

Old Part Number	AO Part Number	Description
M01029_1110	851.110	1.5mm Orbital Rim Plate, 10 holes
M01029_1263	851.263	1.5mm Oblique L-Plate, 6x4 holes, left
M01029_1264	851.264	1.5mm Oblique L-Plate, 6x4 holes, right
M01029_1420	851.420	1.5mm Strut Plate, 2x10 holes
M01029_1421	851.421	1.5mm Strut Plate, 2x18 holes
M01029_1422	851.422	1.5mm Strut Plate, 2x36 holes
M01029_2263	852.263	2.0mm Oblique L-Plate, 6x4 holes, left
M01029_2264	852.264	2.0mm Oblique L-Plate, 6x4 holes, right
M01029_2420	852.420	2.0mm Strut Plate, 2x10 holes
M01029_2421	852.421	2.0mm Strut Plate, 2x18 holes
M01029_1320	851.320	1.5mm Double Y-Plate, 10 holes
M01029_1343	851.343	1.5mm Y-Plate, 4x3x3 holes
M01029_2110	852.110	2.0mm Orbital Rim Plate, 10 holes
M01029_2343	852.343	2.0mm Y-Plate, 4x3x3 holes
M01029_1008	851.008	1.5mm Adaption Plate, 8 holes
M01029_1012	851.012	1.5mm Adaption Plate, 12 holes
M01029_1020	851.020	1.5mm Adaption Plate, 20 holes
M01029_2008	852.008	2.0mm Adaption Plate, 8 holes
M01029_2012	852.012	2.0mm Adaption Plate, 12 holes
M01029_2020	852.020	2.0mm Adaption Plate, 20 holes

- The following plate was updated. A bevel was added to the outer edge and a shallow groove to the center of the top surface in order to give the surgeon tactile feedback indicating the top side of the plate. The addition of these features required that the plate become 0.5mm wider and, 0.5mm longer in order to maintain similar strength. The plate thickness remained the same.
  (For an example of this change see Attachment C)

Old Part Number	AO Part Number	Description
M01029_1604	851.604	1.5mm X-Plate, 4 holes

- The following Mesh Plates were updated. A bevel was added to the outer edge and shallow grooves to the top surface in order to give the surgeon tactile feedback indicating the top side of the plate. The plate's overall size and thickness remained the same.

  (For an example of this change see Attachment D)

Old Part Number	AO Part Number	Description
M01029_1520	851.520	1.5mm Mesh 50x50x0.8 thk
M01029_5010	851.721	1.5mm Straight Row Mesh 50x50x0.8 thk
M01029_5011	851.722	1.5mm Straight Row Mesh 100x100x0.8 thk
M01029_1520	852.520	2.0mm Mesh 48x48x1.2 thk
M01029_1522	851.522	1.5mm Mesh 125x125x0.8 thk
M01029_1521	851.521	1.5mm Mesh 100x100x0.8 thk
M01029_1521	852.521	2.0mm Mesh 78x78x1.2 thk

Conclusion regarding changes to plates:

- Plate strength was retained with this design change as shown below.

Plate Part Number	Average Strength from 510k Testing- 0 Time (previously cleared scalloped style)	Average Strength from Product Quality Testing- 0 Time (new straight side style)	Average Strength from 510k Testing- 8 Weeks (previously cleared scalloped style)	Average Strength from Product Quality Testing- 8 Weeks (new straight side style)
851.008	7.78 N	9.31 N	6.64N	8.30 N

- These changes aid the surgeon in identifying the correct orientation (top side up), therefore, maintaining a low profile. This, in turn, increases patient comfort. Strength, safety, efficacy, indications or marketing claims of the device are not adversely affected by these changes.

Attachment A

(b)(4)

Example Original Style

(b)(4)

Example New Style

Attachment B

(b)(4) [redacted]

Example Original Style

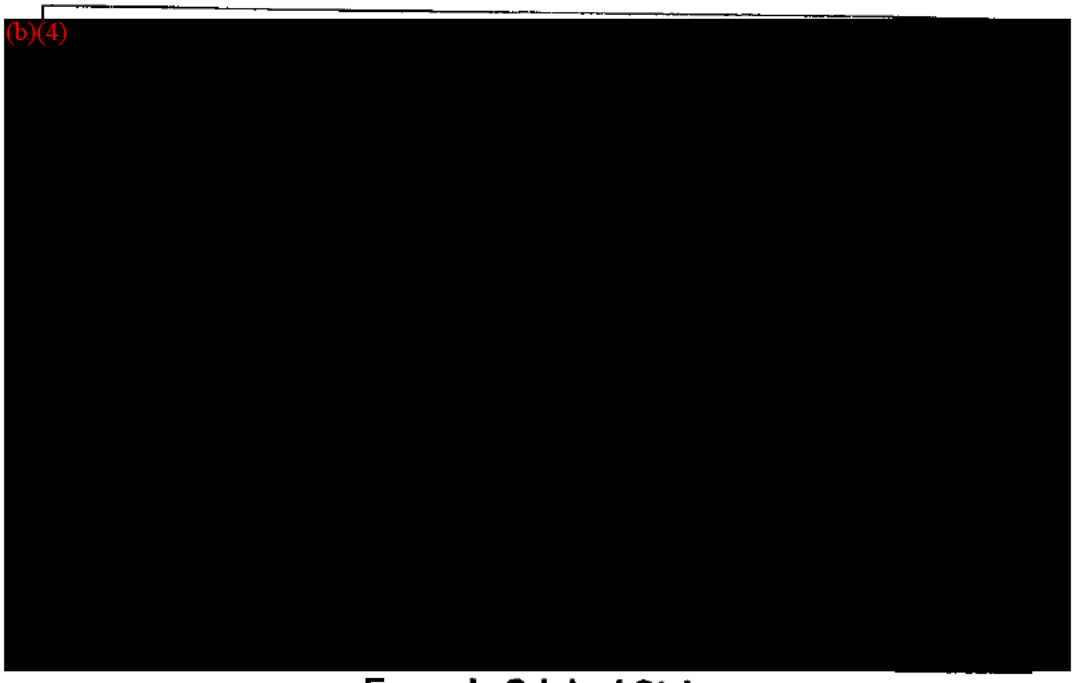
(b)(4) [redacted]

Example New Style

R. Zwirnmann
1/23/2007

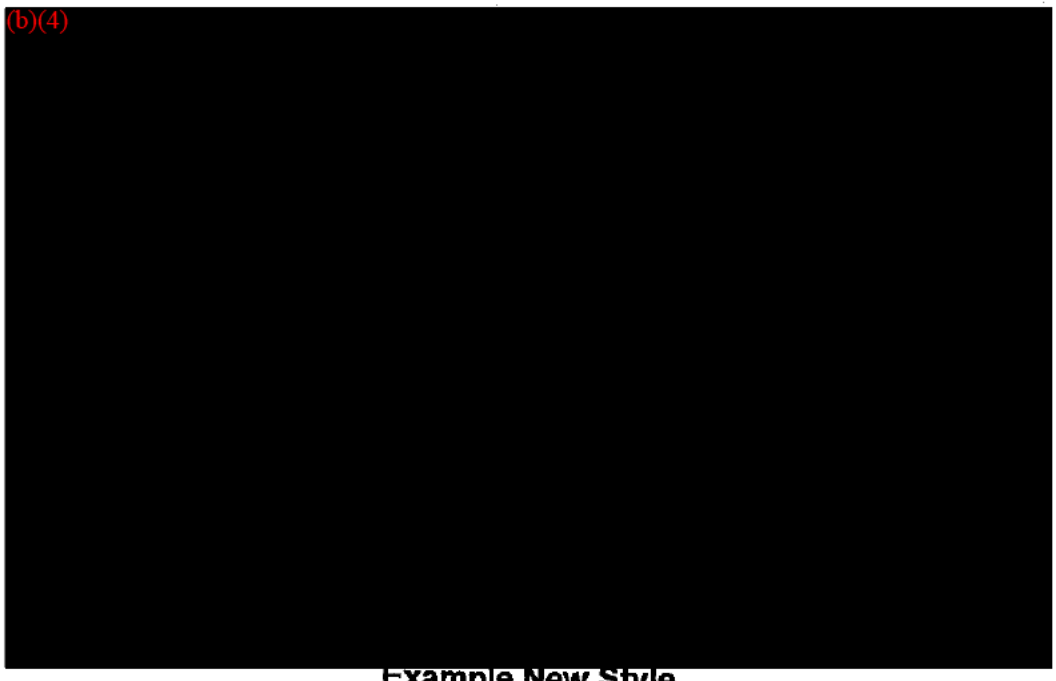
Attachment C

(b)(4)



Example Original Style

(b)(4)



Example New Style

Attachment D

(b)(4)

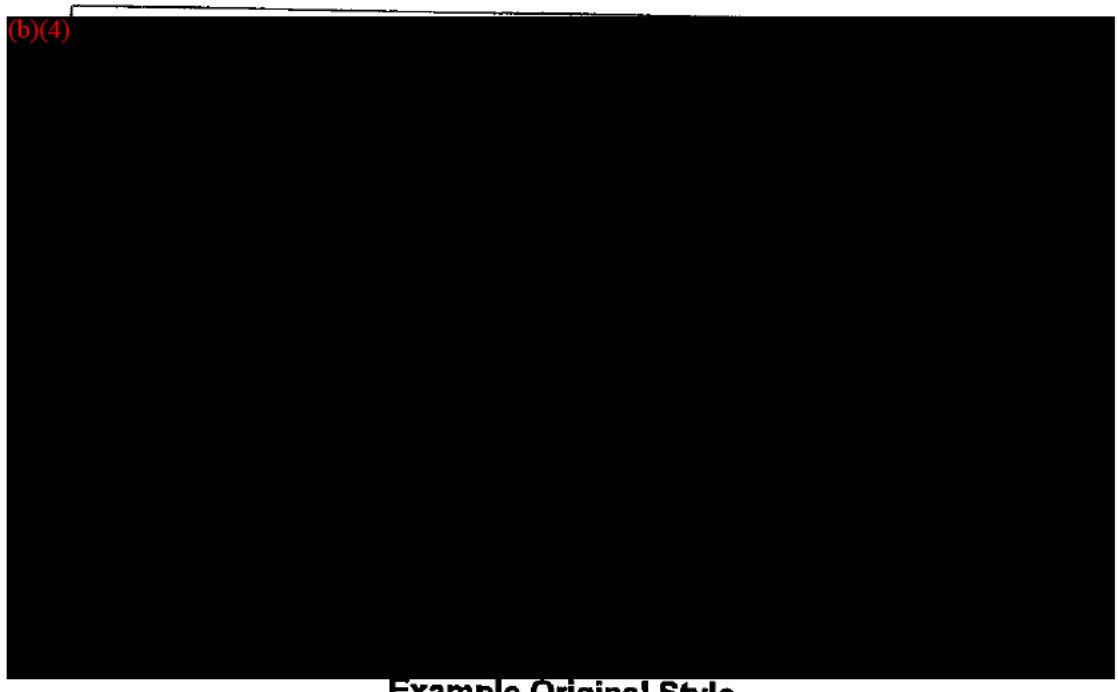
Example Original Style

(b)(4)

Example New Style

Attachment E

(b)(4)



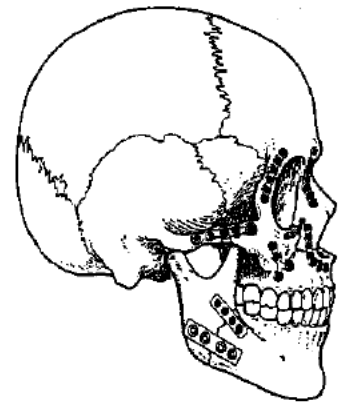
Example Original Style

(b)(4)

Example New Style

Polymer Development

25 January 2007



To: DHF M01-029 Rapid Resorbable System

Cc:

From: Ralph Zwirnmann 26 JAN 07

Re: Addendum to Burr Hole Cover rationale dated 13 August 2003

The following addendum to the above mentioned rationale has been created per FDA faxed questions to 510K submission K062789 dated 11/21/2006. This addendum is to clarify the design modifications mentioned in the rationale dated 13 August 2003.

(b)(4)

Original Style

(b)(4)

New Style

R. Zwirnmann
01/26/2007

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Dow, Jeff

From: Dynesko, Karen
Sent: Monday, January 29, 2007 1:40 PM
To: Dow, Jeff; Klara, Phil; Zwirnmann, Ralph
Subject: RE: K062789/Synthes USA Rapid Resorbable Fixation System

Jeff,

Here is my expanded response. Feel free to adjust wording as appropriate.

Response to question 1: We define pediatrics as age 1 month through 21 years. This is consistent with the FDA Pediatric subpopulations of infant, child, and adolescent. Resorbable implants minimize clinical concerns with metallic plates and screws in the pediatric population including growth restriction and transcranial migration of hardware. The following articles were included in our submission supporting the use of resorbable implants in pediatric patients.

Losken A, MD; Williams J, MD; Burstein F, MD; Cohen S, MD; Hudgins R, MD; Boydston W, MD, PhD; Reisner A, MD; Simms C, RN. **Outcome Analysis for Correction of Single Suture Craniosynostosis Using Resorbable Fixation**. Journal of Craniofacial Surgery 2001; 12:425-455.

Kumar, A, MD; Staffenberg, D, MD; Petronio, J, MD; Wood, R, MD. **Bioabsorbable Plates and Screws in Pediatric Craniofacial Surgery: A Review of 22 Cases.** From the Section of Plastic, Reconstructive & Maxillofacial Surgery and Section of Neurological Surgery, Emory University School of Medicine, Atlanta, GA.

Response to question 2: No additional labeling is anticipated with this new indication. The same technique, instrumentation and implants may be used for either adult or pediatric patients.

Please let me know if you have any questions.

Karen Dynesko
SYNTHES Biomaterials
484-356-9553 Phone
484-356-9591 Fax
Dynesko.Karen@synthes.com

-----Original Message-----
From: Dow, Jeff
Sent: Wednesday, January 24, 2007 2:05 PM
To: Klara, Phil; Dynesko, Karen; Zwirnmann, Ralph
Subject: FW: K062789/Synthes USA Rapid Resorbable Fixation System

Here's the e-mail from Mike Ryan.

-----Original Message-----
From: Ryan, Michael J [mailto:michael.ryan@fda.hhs.gov]
Sent: Wednesday, January 24, 2007 12:00 PM
To: Dow, Jeff
Subject: RE: K062789/Synthes USA Rapid Resorbable Fixation System

Dear Jeff,

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We spoke earlier today regarding the pediatric indications for your device. Please address the following two questions:

1. Is this device indicated for a specific age-range of pediatric patients? As it is currently written, the indications simply mention pediatric populations. Please justify the choice of either a specific age-range or the general pediatric population. You may wish to refer to predicate devices with pediatric indications and any available literature on pediatric use of these devices.
2. Please explain whether the use of these plates in pediatric patients necessitates any additional labeling. Please justify your answer, and again, it may be useful to reference predicate devices with pediatric indications and any available literature.

Thanks for your help, Jeff. Please let me know if you have any questions.

Regards,
Mike Ryan

Michael J Ryan
Biomedical Engineer
Food & Drug Administration
Dental Devices Branch
Phone: 240.276.3717
Fax: 240.276.3789

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