U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K091135 - 130 pages
COMPANY:	BOSTON MEDICAL PRODUCTS, INC. (BOSTMEDIPROD)
PRODUCT:	PROSTHESIS, LARYNX (STENTS AND KEELS) (FWN)
SUMMARY:	Product: RUTTER SUPRA STOMAL STENTS
DATE REQUESTED:	Mar 22, 2016
DATE PRINTED:	Mar 22, 2016
Note:	Printed

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 14 2009

Boston Medical Products, Inc.
c/o Michael A. Warren
117 Flanders Road
Westborough, MA 01581

Re: K091135
Trade/Device Name: Rutter Supra Stomal Stents
Regulation Number: Unclassified
Regulation Name: Prosthesis, Larynx (Stents and Keels)
Regulatory Class: Unclassified
Product Code: FWN
Dated: August 5, 2009
Received: August 5, 2009

Dear Mr. Warren:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091135

SECTION 4: STATEMENT OF INDICATIONS FOR USE

INDICATIONS FOR USE

The Rutter Supra Stomal Stent is indicated for the prevention and treatment of laryngeal and tracheal stenosis.

Prescription Use: __X___ AND/OR Over-the-Counter Use: _____
(Part 21 CFR 807 Subpart C)

DO NOT WRITE BELOW THIS LINE

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K091135

DJA 00001

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 14 2009

Boston Medical Products, Inc.
c/o Michael A. Warren
117 Flanders Road
Westborough, MA 01581

Re: K091135
Trade/Device Name: Rutter Supra Stomal Stents
Regulation Number: Unclassified
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DJA 00002

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

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Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091135

DJA 00003

SECTION 4: STATEMENT OF INDICATIONS FOR USE

INDICATIONS FOR USE

The Rutter Supra Stomal Stent is indicated for the prevention and treatment of laryngeal and tracheal stenosis.

Prescription Use: __X___ AND/OR Over-the-Counter Use: _____
(Part 21 CFR 807 Subpart C)

DO NOT WRITE BELOW THIS LINE

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K091135

DJA 00041

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

June 08, 2009

510k Number: K091135
Product: RUTTER SUPRA STOMAL STENTS

BOSTON MEDICAL PRODUCTS, INC.
117 FLANDERS RD.
WESTBOROUGH, MASSACHUSETTS 01581
UNITED STATES
ATTN: MICHAEL A. WARREN

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.

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 questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 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

DJA 00042

DJA 00059

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

April 29, 2009

510k Number: K091135
Product: RUTTER SUPRA STOMAL STENTS

BOSTON MEDICAL PRODUCTS, INC.
117 FLANDERS RD.
WESTBOROUGH, MASSACHUSETTS 01581
UNITED STATES
ATTN: MICHAEL A. WARREN

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.

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 questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 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

DJA 00060

DJA 00080

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

April 20, 2009

BOSTON MEDICAL PRODUCTS, INC.
117 FLANDERS RD.
WESTBOROUGH, MASSACHUSETTS 01581
UNITED STATES
ATTN: MICHAEL A. WARREN

510k Number: K091135
Received: 4/20/2009
Product: RUTTER SUPRA STOMAL STENTS

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.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at 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).

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

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 procedural questions, please contact the 510(k) 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

DJA 00081

DJA 00082

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s
http://www.fda.gov/cdrh/ode/guidance/1567.html

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html		Not present - OK to proceed per Margie Shelton	
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf		"	
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html	✓		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6	✓		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7	✓		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9	✓		
Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html			✓
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html.			✓
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html. FDA Standards program www.fda.gov/cdrh/stdsprog.html. Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/reqrecstand.html			✓

DJA 00083

Title	Related Information	Present	Inadequate	N/A
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html	✓		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10			
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html	✓		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html	✓		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html			✓
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			✓
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			✓
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			✓
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf			✓

DJA 00084

Title	Related Information	Present	Inadequate	N/A
FORM FDA 3654, *Standards Data Report for 510(k)s - http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf*	**Standards Data Report Form – Form 3654** 1: No standard used - **No Standards Form Required** 2: Declaration of Conformity – **Yes Standards Form Required** 3: Standard but no declaration – **Yes Standards Form Required**		✓ requested 4/23/09 via e-mail	
Kit Certification	Device Advice http://www.fda.gov/cdrh/ode/odecl874.html			✓

Last Updated: 9/3/08 – Brandi Stuart

DJA 00085

Baker, Karen

From: Mike Warren [mwarren@bosmed.com]
Sent: Wednesday, April 22, 2009 2:41 PM
To: Baker, Karen
Subject: RE: k091135

Dear Karen:

Attached is a Summary of Technology for the Rutter Supra Stomal Stent and the cited predicate Lorenz Stent (Ref 510(k) No K896667)

COMPARATIVE INFORMATION

	RUTTER SUPRA STOMAL STENT	LORENZ STENT
MANUFACTURER Inc	Boston Medical Products Inc.	Walter Lorenz Surgical
510(k) NO	K091135 (Pending)	K896667
DESIGN	Prefabricated Molded	Prefabricated Molded
MATERIAL	Silicone Elastomer	Teflon (PTFE)
SIZES 18mm	10 Sizes- Ranging from 6mm-15mm	16 Sizes- Ranging from 6mm to
METHOD OF PLACEMENT	Sutures	Sutures
METHOD OF DEPLOYMENT	Not Applicable	Not Applicable
SUPPLIED STERILE	YES	YES

The Rutter Supra Stomal Stent is a prefabricated tubular device manufactured of silicone elastomer that is supplied in three components. The device has a main tubular body that has a range of outside diameters (6mm - 15mm) and two domed plugs. One plug is fenestrated while the other is solid. Both ends (proximal end is plugged and distal of the device is rounded by prefabricated design) minimize the potential of granulation formation. The Lorenz Stent has the same rounded design feature in both the dome plug end and rounded distal end. The materials of manufacture as sited above allow for ease in customizing the length of the Rutter Supra Stomal Stent that is easily cut to length due to the fact that the material is silicone elastomer while the Lorenz Stent is a more ridged Teflon material that can also be trimmed to length. The Rutter Supra Stomal Stent and the Lorenz Stent have the proximal ends plugged by means of a press fit domed plug. This plug is put in place after approximating the length of the tubular body that is to be used for stenting purposes. The indications for use are the same for both the Rutter Supra Stomal Stent and the Lorenz Stent.

I believe with this additional information and the information I included in Section 9 of the submission you will have a better idea of the device.

DJA 00086

If there is any aspect of either the Supra Stomal Stent or the cited predicate device, the Lorenz Stent, please ask. The devices are quite simple and I have included engineering drawings in Section 9 of the Rutter Supra Stomal Stent. I may be able to get a photograph to you of the stent if that will be of assistance.

Best regards

Michael Warren

From: Baker, Karen [mailto:Karen.Baker@fda.hhs.gov]
Sent: Wednesday, April 22, 2009 11:00 AM
To: Mike Warren
Subject: k091135

Good morning, I'm reviewing the above submission and would like you to send me more information on both your device and the cited predicate device. Please provide a more detailed description of the differences between the two so I have a better understanding of the characteristics of the new device. Thanks

Karen Baker

Karen Baker, MSN, RN
Expert Nurse Consultant
Ear, Nose and Throat Devices Branch
DOED/ODE/CDRH/FDA
240-276-4158
240-276-4156 (fax)
karen.baker@fda.hhs.gov

Total Control Panel Login

To: mwarren@bosmed.com
From: karen.baker@fda.hhs.gov

Message Score: 11
My Spam Blocking Level: Medium

Block this sender
Block fda.hhs.gov

High (60): Pass
Medium (75): Pass
Low (90): Pass

This message was delivered because the content filter score did not exceed your filter level.

DJA 00087

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. 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) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

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

BOSTON MEDICAL PRODUCTS INC
117 FLANDERS ROAD
WESTBOROUGH MA 01581
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
042699348

2. CONTACT NAME
Michael Warren

2.1 E-MAIL ADDRESS
MWarren@Bosmed.com

2.2 TELEPHONE NUMBER (include Area code)
508-898-9300 228

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
508-898-0488

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

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

K14

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

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

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) (4) [redacted]
04-Mar-2009

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

DJA 00088

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5 PREMARKET NOTIFICATON 510(K) STATEMENT

6 CLASS III CERTIFICATION SUMMARY

7 TRUTHFUL AND ACCURATE STATEMENT

8 PROPOSED LABELING AND INSTRUCTIONS FOR USE

9 SPECIFICATIONS AND DESCRIPTION OF DEVICE

10 BIOCOMPATIBILITY

11 STERILIZATION METHOD RESIDUAL TESTING

12 CATOLOG INFORMATION

AVERY READY INDEX® INDEXING SYSTEM 600016

DJA 00089

FDA CDRH DMC

APR 20 2009

Received

SECTION 1: GENERAL INFORMATION

1.	Application Date:	April 15, 2009 510(k) Application
2.	Applicant Identification:	Manufacturer of Device Boston Medical Products, Inc. Attn: Michael A. Warren 117 Flanders Road Westborough, MA 01581 Phone: 508-898-9300 X228 Fax: 508-898-0488 E-Mail: MWARREN@BOSMED.COM
3.	Trade Name	Rutter Supra Stomal Stents (Various Sizes)
4.	Common Name:	Tracheal Stent
5.	Manufacturer FDA Registration:	Boston Medical Product, Inc FDA Registration No. 1219795
6.	Contract Sterilizer Info:	PCS, Inc 40 Miles Standish Blvd Taunton, MA 02780 Phone: 1-508-882-5524 Contact: Gary Cranston
7.	Initial Importer/Distributor:	U.S. Manufacturer Identified in No 2.
8.	Device Classification Name:	Prosthesis, Larynx (Stent and Keels)
9.	Device Regulation Code Number:	Product Code FWN
10.	FDA Device Class:	The FDA has classified this device as a Class II Device (Pre-Amendment)

11. The reason for this 510(k) application is to legally market the device based on substantial equivalence to a predicate device marketed in the United States prior to May 28, 1976. The devices will be sold as sterile single use medical devices.

Predicate Device Identification

Device Description	510(k) Number
Cotton-Lorenz Laryngeal Stent	K896667

12. There are no mandatory Performance Standards or Special Controls required for this device.

DJA 00090

RUTTER SUPRASTOMAL STENT
Instructions for Use

Product Codes

840006 - Size 6 Rutter Stent
840007 - Size 7 Rutter Stent
840008 - Size 8 Rutter Stent
840009 - Size 9 Rutter Stent
840010 - Size 10 Rutter Stent
840011 - Size 11 Rutter Stent
840012 - Size 12 Rutter Stent
840013 - Size 13 Rutter Stent
840014 - Size 14 Rutter Stent
840015 - Size 15 Rutter Stent

Description

The Rutter Suprastomal Stent is a silicone stent system designed to provide support in the stenotic larynx and trachea. The stent is supplied as three components - the main body of the silicone stent, a fenestrated plug and a non-fenestrated plug. The body of the stent has two tapered ends. The tapered end with the smaller diameter hole is designed to lie distally at the tracheostoma and may even slightly overlap the tracheostoma. The proximal end of the stent will accommodate the supplied plugs. The proximal end can be trimmed for custom stent length. The stent system is supplied sterile for single patient use.

Indications For Use

- To aid in the prevention and treatment of laryngeal and tracheal stenosis.

Lifetime of Device

The Rutter Suprastomal Stent is safe and effective for long-term use. In most cases, the stent will be removed upon healing of the surgical repair, typically 4 to 6 weeks. However, from a material standpoint, the stent may be used on a longer-term basis at the discretion of the physician. BMPI recommends the maximum lifetime of this device to be six months after insertion, after which time it should be replaced with a new device.

Contraindications

1. Care must be taken to smooth any shortened or modified intraluminal limb of the Rutter Stent prior to insertion.
2. The Rutter Stent must be used simultaneously with a tracheostomy tube.

Precautions

1. Federal Law (USA) restricts this product to sale by or on the order of a physician.
2. Read instructions prior to use.
3. This product is for single patient use only

DJA 00091

SECTION 2: TABLE OF CONTENTS

See front cover for Table of Contents

DJA 00092

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

See Related Information

510(k) Number: _____

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

- ☐ Special 510(k) - Do Sections 1 and 2
- ☐ Abbreviated 510(k) - Do Sections 1, 3 and 4
- ☐ 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 in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		

DJA 00093

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:

	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		

DJA 00094

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:		

DJA 00095

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:_____

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

Uploaded on March 3, 2004

DJA 00096

SECTION 4: STATEMENT OF INDICATIONS FOR USE

INDICATIONS FOR USE

The Rutter Supra Stomal Stent is indicated for the prevention and treatment of laryngeal and tracheal stenosis.

Prescription Use: __X___ AND/OR Over-the-Counter Use: _____
(Part 21 CFR 807 Subpart C)

DO NOT WRITE BELOW THIS LINE

_____
Concurrence of CDRH, Office of Device Evaluation

DJA 00097

SECTION 5: 510(k) Premarket Notification Statement

Mr. Stuart Montgomery, President of Boston Medical Products, Inc. acting as the Official Correspondent has included the Notification Statement.

DJA 00098

Boston
Medical Products

PREMARKET NOTIFICATION STATEMENT

PREMARKET NOTIFICATION
510(k) STATEMENT
(Required by 21 CFR 807.93)

I certify, in my capacity as President and Official Correspondent of Boston Medical Products, Inc., with a primary business location of 117 Flanders Road, Westborough, MA 01581, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding patient identifiers, trade secrets and confidential commercial information as defined in 21 CFR 20.61

Signature of Certifier

Stuart K. Montgomery, President
Typed Name and Title

15-APR-09
Date

Boston Medical Products, Inc.
117 Flanders Road, Westborough, MA 01581 USA
Customer Service: 1-800-433-BMPI (2674)
Tel: 508-898-9300 • Fax: 508-898-2373
www.bosmed.com | www.trachs.com

DJA 00099

SECTION 6: CLASS III CERTIFICATION AND SUMMARY

This Certification and Summary are not applicable for this submission.

DJA 00100

SECTION 7: TRUTHFUL AND ACCURATE STATEMENT

A Truthful and Accurate Statement will be included in this section by Mr Stuart Montgomery, President of Boston Medical Product, Inc. Westborough, MA 01581.

DJA 00101

Boston
Medical Products

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as President of Boston Medical Products, Inc., of 117 Flanders Road, Westborough MA 01581, 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.

Signature of Official Correspondent

Stuart K. Montgomery
Typed Name

3/4/09
Date

Boston Medical Products, Inc.
117 Flanders Road, Westborough, MA 01581 USA
Customer Service: 1-800-433-BMPI (2674)
Tel: 508-898-9300 • Fax: 508-898-2373
www.bosmed.com | www.trachs.com

DJA 00102

Insertion Technique - Surgical

1. The stent will usually be placed during open laryngotracheal airway surgery through an anterior cricoid split.
2. The stent is designed to be held in place by transfixation suture technique. Once the distal end of the stent is positioned to lie at the tracheostoma, a transfixation suture using 3.0 non-absorbable monofilament is placed. The suture should pass through the strap muscles on the left side of the neck, through the tracheal or cricoid wall, through the stent, and then exit the tracheal or cricoid cartilage, and pass through the strap muscles on the right side of the neck.
3. Clamps are applied to either end of the transfixation suture, but the suture is not yet tied.
4. The proximal end of the stent is now visualized by an assistant with a laryngoscope, and the stent removed from the wound and trimmed to the proper length such that the stent lies at level of the false cord. The stent can be trimmed using a Safe-T-Tube cutter or scissors.
5. Once satisfied with the proximal placement of the stent, the plug can be inserted. The fenestrated plug is the preferred plug as this allows for limited vocalization in some patients, and in the event of a tracheostomy occlusion or displacement, will allow for limited airflow through the stent. The non-fenestrated plug is supplied for use in patients with a high risk of aspiration. The plug is inserted into the proximal end such that is should not be displaced and should lie at the mid-epiglottic level. The smooth tapered design minimizes the risk of epiglottis granulation.
6. The airway may now be closed, including placement of cartilage grafts or anastomotic sutures. Once the strap muscles are re-opposed, the transfixation sutures may be tied. A 1-2 cm segment of angiocath is threaded over the left-hand end of the suture, and the suture then tied with a knot lying on the right side of the neck.
7. Approximately 20-30 throws of the knot are recommended to allow the suture to be easily found when the stent is to be removed.
8. The neck wound is then closed with the knot of the transfixation suture lying just beneath the skin.

Insertion Technique - Endoscopic

1. Occasionally it is desirable to endoscopically place a suprastomal stent. This may be challenging, and ideally should only be attempted in a patient with a thin neck, and with an assistant endoscopically guiding the surgeon.
2. The stent is designed as a transglottic suprastomal stent and therefore should only be used in patients with a tracheotomy.
3. The indications for consideration of an endoscopically placed stent include posterior cordotomy, endoscopic management of posterior glottic stenosis, and salvage stenting following laryngotracheal reconstruction.
4. The size of stent is determined by the anticipated size of the subglottis – for example a 4 year old child should accommodate a 5.0 endotracheal tube with an outer diameter of 6.8mm, therefore a 7mm stent would be selected (although a 6mm or 8mm stent could also be used). If the airway is stenotic, dilation may be required prior to stent insertion, and dilation with a balloon dilator 1mm greater in diameter than the size of the stent is ideal.
5. The stent is endoscopically inserted, with the tapered end (with the smaller lumen) distally, so that the end of the stent is just in contact with the tracheotomy tube. This may be established with either an endoscope placed through the tracheotomy to visualize the tip of the stent, or with a small Hopkins rod telescope placed inside the stent to visualize the tracheotomy tube.
6. The stent is then removed and trimmed to length so that the proximal cut end of the stent lies at false vocal cord level, while the distal end of the stent lies just at the stoma site.

DJA 00103

7. The stent is reinserted into the airway.
8. Local anesthetic with epinephrine is infiltrated on either side of the neck approximately at the level of the cricoid cartilage.
9. A stab incision is made on the right side of the neck, and forceps used to bluntly dissect down to the mid point of the cricoid cartilage.
10. A long heavy Keith needle is selected, and a 3.0 non-absorbable monofilament suture (e.g. Prolene, 36 inch) threaded through it. It is useful to bend the tip of the needle so that it resembles the letter "J".
11. Then the needle is placed through the cricoid cartilage and into the lumen of the stent, where it is visualized by a Hopkin's rod endoscope placed into the lumen of the stent by the assistant surgeon. ***This is the most challenging part of the procedure, and may take several attempts.***
12. Once the Keith needle is visualized, it may then be passed through the stent, through the left side of the cricoid cartilages and into the soft tissues of the neck until it can be palpated subcutaneously. Care must be taken not to damage the great vessels, and the needle should pass anterior and medial to the great vessels.
13. A stab incision is placed over the needle tip, and the needle withdrawn from the neck.
14. The stent is now pedicled on the 3.0 suture which is passing through the stab incisions placed on either side of the neck.
15. Clamps are placed on the distal aspects of the transfixion suture, and keeping these taunt, the stent is removed from the airway, so that it is visible in the mouth, and the cap (fenestrated or unfenestrated) is then inserted.
16. Pulling on the sutures (and taking care not to twist them in the oral cavity), the stent is replaced in the airway.
17. Once satisfied with stent position, a forcep is placed through the right-sided stab incision, and bluntly tunneled (between skin and trachea) until it protrudes from the left neck incision.
18. The tip of the suture in the left neck is grasped in the forceps, and the suture withdrawn from the right side of the neck. This end of the suture then has a 1-2cm segment of 16G angiocath threaded over it, and the suture then tied with a knot lying on the right side of the neck. Approximately 20-30 throws of the knot are recommended to allow the suture to be easily found when the stent is to be removed.
19. The neck wounds are then closed with the knot of the transfixion suture lying just beneath the skin.
20. If difficulty is encountered with passing the Keith needle through the stent, it may be necessary to place a much larger transverse neck incision, and place the transfixion suture with the cricoid fully exposed.

Removal Technique

1. Removal of the stent is identical whether the stent has been placed during open airway reconstruction or endoscopic procedure.
2. Stent removal may be performed between 10 days and 6 months. The usual term of implantation is 4-6 weeks.
3. A small incision is made over the knot of the transfixation suture and dissected down to the angiocath.
4. The suture is cut and the suture and angiocath are removed from the neck.
5. An assistant meanwhile will remove the stent endoscopically from the larynx.

DJA 00104

Warranty

Boston Medical Products, Inc. (BMPI) warrants that reasonable care has been used in the manufacturing of this device. As a result of biological differences in individuals, no product is 100% effective under all circumstances. Because of this fact and since we have no control over the conditions under which this device is used, diagnosis of the patient, methods of administration, or its handling after the device leaves our possession, BMPI does not warrant a good effect or against an ill effect following its use.

The physician must use this device based on his/her own medical training and experience. All medical professionals directly or indirectly using this device are responsible for its proper use.

BMPI shall not be liable for any incidental or consequential loss, damage or expense arising directly from the use of this product. BMPI will replace any device we determine to be defective at the time of shipment. BMPI may offer specific warranty periods for different products. Please call Customer Service for details. No representative of BMPI may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

Please direct any inquiries regarding this device to:

Boston Medical Products, Inc.
117 Flanders Road, Westborough, MA 01581 USA
Tel: (508) 898-9300 Fax: (508) 898-2373

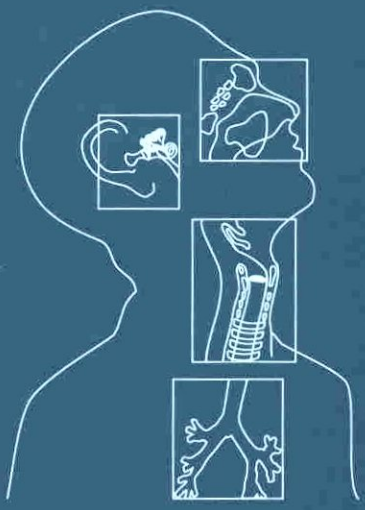
(b) (4)

[redacted]

DJA 00105

EXAMPLE

CARTON LABELING



Rutter Stent

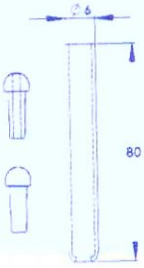
Size: Size 6mm, Type: white

DE:
FR:
ES:
IT:
PT:
SE:

REF 840006

CE 0086

QTY 1 | STERILE EO



HB427A

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

Rutter Stent

Size: Size 6mm, Type: white

REF 840006 LOT Sample 2009-04

Boston Medical Products, Inc.
Westborough, MA (USA) | www.bosmed.com

L09A

106

Boston Medical Products, Inc.
Westborough, MA 01581 USA

T: 508-898-9300
F: 508-898-2373

info@bosmed.com
www.bosmed.com
www.trachs.com

TO EXPOSE ADHESIVE REMOVE

Boston
Medical Products

PRESS AND REMOVE TO OPEN
CONTENTS NOT RETURNABLE IF SEAL IS BROKEN

Boston Medical Products, Inc.
Westborough, MA 01581 USA

T: 508-898-9300
F: 508-898-2373

info@bosmed.com
www.bosmed.com
www.trachs.com

03 1
09

107

DJA 00108

EXAMPLE

INNER POUCH LABELING

DJA 00109

PEEL TO OPEN

STERILE EO

CONTENTS STERILE
unless seal is broken or package opened or damaged. Do not re-sterilize this product.

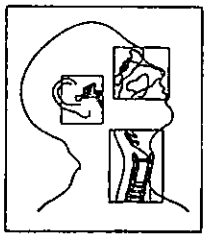
This product is for single patient use only.

Read enclosed product information prior to use.

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

Boston Medical Products

Boston Medical Products, Inc.
Westborough, MA 01581 USA



REF 840006

Rutter Stent

Size 6mm, white

LOT Sample 2009-04

Boston Medical Products, Inc.
Westborough, MA (USA)

QTY 1

STERILE EO

P47A

DJA 00110

EXAMPLE

OUTER POUCH LABELING

DJA 00111

PEEL TO OPEN

STERILE EO

CONTENTS STERILE
unless seal is broken or package opened or damaged. Do not re-sterilize this product.

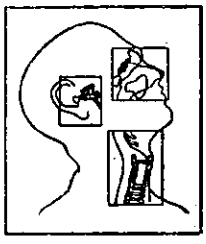
This product is for single patient use only.

Read enclosed product information prior to use.

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

Boston Medical Products

Boston Medical Products, Inc.
Westborough, MA 01581 USA



REF 840006

Rutter Stent

Size 6mm, white

LOT Sample 2009-04

Boston Medical Products, Inc.
Westborough, MA (USA)

QTY 1

STERILE EO

P510A

DJA 00112

SECTION 9: SPECIFICATIONS AND DESCRIPTION OF DEVICE

DEVICE DESCRIPTION:

The Rutter Supra Stomal Stent is manufactured of a soft but compliant silicone elastomer material that is suitable to support a stenotic trachea or larynx for the indications for use as defined. The stent is supplied as three components- the main body of the stent, a fennestrated plug and a non-fennestrated plug. The body of the stent has two tapered ends. The tapered end with the smaller diameter hole is designed to lie distally at the tracheostoma and may even slightly overlap the tracheostoma. The proximal end of the stent will accommodate one of the supplied plugs. The proximal end can be trimmed to length for exact fitting. The standard plug is fennestrated to allow a limited amount of air flow for voicing. The non-fennestrated plug is supplied for use in patients with a particular high risk of aspiration. Both the proximal plugged end of the stent and the distal end of the stent are rounded and smooth by design as to minimize the potential for granulation tissue formation. The plugs are pressed fit into place and do not require glueing or suturing to prevent displacement. The Rutter Supra Stomal Stent are available in a size range from 6mm-15mm in outside diameter. The lengths of the stents range from 80mm to 125mm depending on the size. Engineering drawings and specifications for the full range of available sizes of the Rutter Supra Stomal Stents are included in Section 9.

PACKAGING AND STERILIZATION:

The device is supplied as "Sterile" by means of (b) (4) [redacted]. The packaging scheme will be a double pouched and sealed. There will be a copy of the Information for Use contained within each carton. Each carton will contain one device as labeled. Packaging is performed after a validated cleaning process. This cleaning process and packaging is performed in a clean room environment under laminar flow benches prior to terminal sterilization. Secondary packaging consisting of placing the device, post-sterilization, in a display carton with the Information for use and outer carton label. An example of the pouch and carton label are included in Section 8.

COMPARATIVE INFORMATION, SUBSTANTIAL EQUIVALENCE

The Rutter Supra Stomal Stent is substantially equivalent to the predicate device (Ref K896667-Lorenz Stent). The indications for use for both the Rutter Supra Stomal Stent and the predicate are exactly the same. The design features of the Rutter Supra Stomal Stent and the predicate are similar in that the devices are tubular in fashion and have a proximal end that can accommodate a cap. The Rutter Supra Stomal Stent and the predicate device both have rounded proximal and distal aspects of the device that help to minimize the potential of the formulation of granulation tissue. The Rutter Supra Stomal Stent has the added option of using a fennestrated plug for the purpose as indicated. The Rutter Supra Stomal Stent is easily modified in length by simply trimming from the proximal end of the stent that will be later capped with one of the supplied plugs. The materials of manufacture are different in that the Rutter Supra Stomal Stent is fabricated of an Implant Grade Silicone Elastomer while the Lorenz Stent is fabricated of Teflon. Both materials are biocompatible, allow for the similar design features while maintaining the same indications for use.

DJA 00113

The Rutter Supra Stomal Stent has the availability of a wide range of outside diameter sizes (6mm-15mm) while the lengths are easily adjusted by trimming to length for an exact fit. Ease of customizing the Rutter Supra Stomal Stent's length is advantageous during the surgical procedure and easily fitted.

(b)(4)Design

(b)(4)Design

(b)(4)Design

(b)(4)Design

(b)(4)Design

(b)(4)Design

(b)(4)Design

(b)(4)Design

(b)(4)Design

(b)(4)Design

DJA 00124

SECTION 10: BIOCOMPATIBILITY

The Rutter Supra Stomal Stents are manufactured of (b) (4) [redacted] Elastomer. This implant grade of silicone elastomer is termed "Unrestricted" by the manufacturer and can be used for devices that are intended to be in place for greater than 30 Days.

(b) (4) [redacted]

(b)(4)Product Specs

(b)(4)Product Specs

DJA 00127

TECHNICAL BULLETIN

Boston Medical Products, Inc.

117 Flanders Road, Westborough, MA 01581
CUSTOMER SERVICE: 1-800-433-2674
Tel: (508) 898-9300 Fax: (508) 898-2373
www.bosmed.com / www.trachs.com

Bulletin SRD-RSS-A 4/09

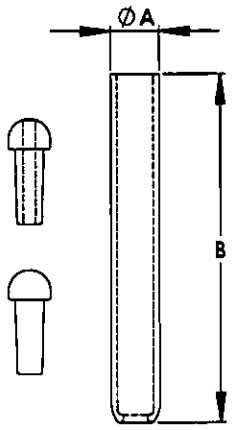
PRODUCT: RUTTER SUPRASTOMAL STENT

DESCRIPTION:

The Rutter Suprastomal Stent is a silicone stent system designed to provide support in the stenotic larynx and trachea. The stent is supplied as three components - the main body of the silicone stent, a fenestrated plug and a non-fenestrated plug. The body of the stent has two tapered ends. The tapered end with the smaller diameter hole is designed to lie distally at the tracheostoma and may even slightly overlap the tracheostoma. The proximal end of the stent will accommodate the supplied plugs. The proximal end can be trimmed for custom stent length. The stent system is supplied sterile for single patient use.

SIZING and ORDERING INFORMATION:

Description	Size	A	B
Size 6 Rutter Stent	6	6mm	80mm
Size 7 Rutter Stent	7	7mm	80mm
Size 8 Rutter Stent	8	8mm	80mm
Size 9 Rutter Stent	9	9mm	90mm
Size 10 Rutter Stent	10	10mm	90mm
Size 11 Rutter Stent	11	11mm	100mm
Size 12 Rutter Stent	12	12mm	125mm
Size 13 Rutter Stent	13	13mm	125mm
Size 14 Rutter Stent	14	14mm	125mm
Size 15 Rutter Stent	15	15mm	125mm



REF									
Size 6	Size 7	Size 8	Size 9	Size 10	Size 11	Size 12	Size 13	Size 14	Size 15
840006	**840007**	**840008**	**840009**	**840010**	**840011**	**840012**	**840013**	**840014**	**840015**

DJA 00004

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

COVER SHEET MEMORANDUM

From: Reviewer Name Vasant G. Malshet

Subject: 510(k) Number K091135/S2

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

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

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary / 510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

DJA 00005

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

Regulation Number unclassified, **Class*** unclassified **Product Code** FWN

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

Additional Product Codes:

Review: [signature] ENTB 09/11/09

(Branch Chief) (Branch Code) (Date)

Final Review: [signature] 9/14/09

(Division Director) (Date)

DJA 00006

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

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

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

K091135/S002

Date: August, 17, 2009
To: The Record
From: Vasant G. Malshet, Ph.D., DABT
510(k) Holder: Boston Medical Products
Device Name: Rutter Supra Stomal Stents
Contact: Michael A. Warren
Phone: 508-898-9300 X228
Fax: 508-898-0488
Email: mwarren@bosmed.com

Office: ODE
Division: DONED

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Rutter Supra Stomas Stents into interstate commerce.

II. Administrative Requirements

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

III. **Device Description**: The Rutter Suprastomal Stent is a silicone stent system designed to provide support in the stenotic larynx and trachea. The stent is supplied as three components- the mail body of the silicone stent, a fenestrated plug and a non-fenestrated plug. The body of the stent has two tapered ends. The tapered end with the smaller diameter hole is designed to lie distally at the tracheostoma and may even slightly overlap the tracheostoma. The proximal end of the stent will accommodate the supplied plugs. The proximal end can be trimmed for custom stent length. The stent system is sterile for single patient use.

The fenestrated plug is the preferred plug as this allows for limited vocalization in some patients, and in the event of a tracheotomy occlusion or displacement, will allow for limited airflow thorough the stent. The non-fenestrated plug is supplied for use inpatients with a high risk of aspiration.

The stent is intended for long-term use. In most cases, the stent will be removed upon healing of the surgical repair, typically 4 to 6 weeks. However, from a material standpoint, the stent may be used on a longer-term basis at the discretion of the physician. The firm recommends that the maximum lifetime of the device be six months after insertion, after

DJA 00007

which time it should be replaced with a new device.

The device will be supplied in several sizes: size 6 mm to size 15 mm.

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

IV. **Indications for Use**: The Rutter Supra Stomas Stent is indicated for the prevention and treatment of laryngeal and tracheal stenosis.

V. **Predicate Device Comparison**: Lorenz Stent, K896667, indicated for

1. Chronic glottic and subglottic stenosis. Stenting after division of posterior cricoid lamina, with or without cartilage graft.

2. Combined chronic upper tracheal stenosis with or without laryngeal stenosis.

Subject device/predicate device comparative information:

	RUTTER SUPRA STOMAL STENT	LORENZ STENT
MANUFACTURER Inc	Boston Medical Products Inc.	Walter Lorenz Surgical
510(k) NO	K091135 (Pending)	K896667
DESIGN	Prefabricated Molded	Prefabricated Molded
MATERIAL	Silicone Elastomer	Teflon (PTFE)
SIZES	10 Sizes- Ranging from 6mm-15mm	16 Sizes- Ranging from 6mm to 18mm
METHOD OF PLACEMENT	Sutures	Sutures
METHOD OF DEPLOYMENT	Not Applicable	Not Applicable

DJA 00008

SUPPLIED STERILE	YES	YES

IV. **Labeling**: Sample labeling is provided including device description, indications for use, contraindications, precautions, and surgical techniques.

V. **Sterilization/Shelf Life/Reuse**: The devices are provided sterile, single use. See attached sterilization review sheet.

VI. **Biocompatibility**: (see attached Biocompatibility review) the review of original submission Dr. Malshet requested the following information

The 13 week implantation study in the (b) (4) [redacted] showed slight irritation. Therefore, I recommend that the sponsor add a caution statement to the labeling stating, "The material in this device has been shown in biocompatibility studies to cause slight irritation". Also since this device will be in patient contact for more than 30 days, the sterilization method used in the studies carried out in the master file are not the same, and just to make sure that nothing is leaching out of silicone during the manufacturing device, the company should provide cytotoxicity (direct contact method) study data on final sterilized product. Alternatively the company can provide an adequate scientific justification for not adding the caution statement and providing the cytotoxicity data.

In supplement S001, the company added the following caution statement (S001): "The Rutter Supra-Stomal Stent is safe and effective for long term use. In most cases the stent will be removed between 4-6 weeks upon healing of the surgical repair. The stent maybe used for an extended period but biological testing of the material used has shown a "slight irritation" in the 13 week biocompatibility implant test." According to Dr. Malshet, this statement is acceptable.

In Supplement S002, the company submitted cytotoxicity study (direct contact method) according to ISO 10993-5. The test results shows the patient contact material in not toxic.
Per Dr. Malshet, the company has provided adequate information and he does not have any more questions.

VII. **Software**: There is no software in the device.

VII. **Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**: There are no mechanical or electrical parts so there are no EMC, mechanical or thermal safety concerns.

VIII. **Performance Testing – Bench**: No bench testing is provided.

X. **Performance Testing – Animal**: No animal testing is provided.

XI. **Performance Testing – Clinical**: No clinical testing is provided.

DJA 00009

XII. Substantial Equivalence Discussion

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

XIII. Contact History

April 22, 2009, e-mail sent to sponsor requesting additional subject/predicate device comparison.
April 23, 2009, e-mail sent to sponsor requesting standards data report sheet.
April 27, 2007, e-mail sent to sponsor requesting the above biocompatibility/toxicology information.

XIV. Recommendation:

Regulation Number: Unclassified
Regulation Name: Prosthesis, Larynx (stents and keels)
Regulatory Class: Unclassified
Product Code: FWN

Reviewer — Date 8/17/09

Branch Chief — Date 9/11/09

DJA 00010

REVIEW OF TOXICOLOGY DATA

Date : August 17, 2009
From: : Vasant G. Malshet, Ph.D., DABT **Division/Branch:** DONED
To : Karen baker, RN **Division/Branch:** DONED
Trade Name: Rutter Supra stomal Stent
510(k) # : K091135/S002
Applicant : **Boston Medical Products**

In my review of original submission I requested the following information

The 13 week implantation study in the (b) (4) [redacted] showed slight irritation. Therefore, I recommend that the sponsor add a caution statement to the labeling stating, "The material in this device has been shown in biocompatibility studies to cause slight irritation". Also since this device will be in patient contact for more than 30 days, the sterilization method used in the studies carried out in the master file are not the same, and just to make sure that nothing is leaching out of silicone during the manufacturing device, the company should provide cytotoxicity (direct contact method) study data on final sterilized product. Alternatively the company can provide an adequate scientific justification for not adding the caution statement and providing the cytotoxicity data.

The company added the following caution statement (S001): "**The Rutter Supra-Stomal Stent is safe and effective for long term use. In most cases the stent will be removed between 4-6 weeks upon healing of the surgical repair. The stent maybe used for an extended period but biological testing of the material used has shown a "slight irritation" in the 13 week biocompatibility implant test."** This statement is acceptable

In this submission (S002), the company submitted cytotoxicity study (direct contact method) according to ISO 10993-5. The test results shows the patient contact material in not toxic.

I do not have any biocompatibility questions.

Vasant G. Malshet, Ph.D., DABT
Expert Toxicologist

DJA 00043

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

COVER SHEET MEMORANDUM

From: Reviewer Name Karen Baker

Subject: 510(k) Number K091135 / S1

To: The Record

Please list CTS decision code TH incomplete contents

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

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

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single-use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

DJA 00044

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

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

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

Additional Product Codes:

Review: ENTD 6/4/09

(Branch Chief) (Branch Code) (Date)

Final Review:

(Division Director) (Date)

DJA 00045

Date: June 4, 2009
To: The Record
From: Karen Baker

Subject: K091135 S001
Boston Medical Products

This submission is in response to a hold placed on the original for missing biocompatibility information. Vasant Malshet, PhD, DOED toxicologist reviewed the response and stated that all of the requested information was not provided. The submission does not contain the cytotoxicity study information requested.

The submission is placed on hold again because the sponsor did not provide the requested information. I had an e-mail exchange with the sponsor regarding the missing material. He stated he knew the information was not included and would send it in as soon as available. A copy of the e-mail is attached.

Based on this, the file is placed on hold pending receipt of the remaining biocompatibility information.

Karen Baker

Karen Baker, MSN, RN
Nurse Consultant/ENTB

DJA 00046

Baker, Karen

From: Mike Warren [mwarren@bosmed.com]
Sent: Thursday, June 04, 2009 12:40 PM
To: Baker, Karen
Subject: RE: K091135

Hi Karen:

Thanks you. It is in process.

Best regards,

Mike

From: Baker, Karen [mailto:Karen.Baker@fda.hhs.gov]
Sent: Thursday, June 04, 2009 12:19 PM
To: Mike Warren
Subject: RE: K091135

OK, We'll put it back on hold, then.

Karen

From: Mike Warren [mailto:mwarren@bosmed.com]
Sent: Thursday, June 04, 2009 12:11 PM
To: Baker, Karen
Subject: RE: K091135

Hello Karen:

Yes, I know that was left out. The situation is that samples of the Rutter-Suprastomal Stents are included on Sterile Load 122. The Testing is being conducted by (b) (4) [redacted]. When the results are delivered, I will forward them in the same fashion as the IFU update.

I will send you scanned copies of the results and the hard copies to the 510k Major Resource Document Center.

Regards

Michael Warren

From: Baker, Karen [mailto:Karen.Baker@fda.hhs.gov]
Sent: Thursday, June 04, 2009 9:01 AM
To: Mike Warren
Subject: K091135

Dear Mike, We had requested some additional information as below:

(b) (4) [redacted]

DJA 00047

Silicone Elastomer does not cause cytotoxicity, hemolysis, sensitization, acute systemic toxicity, intracutaneous toxicity, hemolysis, pyrogenicity, and mutation in bacterial cells. The Seven-day muscle implantation study did not show any irritation; however, the 13 week implantation study in the (b) (4) [redacted] *showed slight irritation. Therefore, we recommend that you add a caution statement to the labeling stating, "The material in this device has been shown in biocompatibility studies to cause slight irritation".*

In addition, since this device will be likely have patient contact for more than 30 days and the sterilization method used in the studies carried out in the master file is not the same, please provide cytotoxicity (direct contact method) study data on the final sterilized product. Alternatively you may provide an adequate scientific justification for not adding the caution statement and providing the cytotoxicity data.

You responded that the caution statement would be added to the Instructions for use but we do not find the cytotoxicity data. Please provide this information as requested above and in our earlier e-mail dated April 28, 2009

Karen
Karen Baker, MSN, RN
Expert Nurse Consultant
Ear, Nose and Throat Devices Branch
DOED/ODE/CDRH/FDA
240-276-4158
240-276-4156 (fax)
karen.baker@fda.hhs.gov

Total Control Panel

To: mwarren@bosmed.com
From: karen.baker@fda.hhs.gov

Message Score: 1
My Spam Blocking Level: Medium

Block this sender
Block fda.hhs.gov

High (60): Pass
Medium (75): Pass
Low (90): Pass

This message was delivered because the content filter score did not exceed your filter level.

Total Control Panel Login

To: mwarren@bosmed.com
From: karen.baker@fda.hhs.gov

Message Score: 19
My Spam Blocking Level: Medium

Block this sender
Block fda.hhs.gov

High (60): Pass
Medium (75): Pass
Low (90): Pass

This message was delivered because the content filter score did not exceed your filter level.

DJA 00048

Baker, Karen

From: Mike Warren [mwarren@bosmed.com]
Sent: Thursday, June 04, 2009 12:11 PM
To: Baker, Karen
Subject: RE: K091135

Hello Karen:

Yes, I know that was left out. The situation is that samples of the Rutter-Suprastomal Stents are included on Sterile Load 122. The Testing is being conducted by (b) (4) [redacted]. When the results are delivered, I will forward them in the same fashion as the IFU update.

I will send you scanned copies of the results and the hard copies to the 510k Major Resource Document Center.

Regards

Michael Warren

From: Baker, Karen [mailto:Karen.Baker@fda.hhs.gov]
Sent: Thursday, June 04, 2009 9:01 AM
To: Mike Warren
Subject: K091135

Dear Mike, We had requested some additional information as below:

The (b)(4)Product Specs [redacted] *shows that the patient contacting material* (b) (4) [redacted] (b)(4)Product [redacted] *does not cause cytotoxicity, hemolysis, sensitization, acute systemic toxicity, intracutaneous toxicity, hemolysis, pyrogenicity, and mutation in bacterial cells. The Seven-day muscle implantation study did not show any irritation; however, the 13 week implantation study in the* (b) (4) [redacted] *showed slight irritation. Therefore, we recommend that you add a caution statement to the labeling stating, "The material in this device has been shown in biocompatibility studies to cause slight irritation".*

In addition, since this device will be likely have patient contact for more than 30 days and the sterilization method used in the studies carried out in the master file is not the same, please provide cytotoxicity (direct contact method) study data on the final sterilized product. Alternatively you may provide an adequate scientific justification for not adding the caution statement and providing the cytotoxicity data.

You responded that the caution statement would be added to the Instructions for use but we do not find the cytotoxicity data. Please provide this information as requested above and in our earlier e-mail dated April 28, 2009

Karen
Karen Baker, MSN, RN
Expert Nurse Consultant
Ear, Nose and Throat Devices Branch
DOED/ODE/CDRH/FDA
240-276-4158
240-276-4156 (fax)
karen.baker@fda.hhs.gov

DJA 00049

Total Control Panel Login

To: mwarren@bosmed.com
From: karen.baker@fda.hhs.gov

Message Score: 1
My Spam Blocking Level: Medium

Block this sender
Block fda.hhs.gov

High (60): Pass
Medium (75): Pass
Low (90): Pass

This message was delivered because the content filter score did not exceed your filter level.

DJA 00050

REVIEW OF TOXICOLOGY DATA

Date : June 4, 2009
From: : Vasant G. Malshet, Ph.D., DABT **Division/Branch:** DOED
To : Karen baker, RN **Division/Branch:** DOED
Trade Name: Rutter Supra stomal Stent
510(k) # : K091135/S01
Applicant : **Boston Medical Products**

In my review I requested the following information

The 13 week implantation study in the (b) (4) [redacted] showed slight irritation. Therefore, I recommend that the sponsor add a caution statement to the labeling stating, "The material in this device has been shown in biocompatibility studies to cause slight irritation". Also since this device will be in patient contact for more than 30 days, the sterilization method used in the studies carried out in the master file are not the same, and just to make sure that nothing is leaching out of silicone during the manufacturing device, the company should provide cytotoxicity (direct contact method) study data on final sterilized product. Alternatively the company can provide an adequate scientific justification for not adding the caution statement and providing the cytotoxicity data.

The company added the following caution statement: "**The Rutter Supra-Stomal Stent is safe and effective for long term use. In most cases the stent will be removed between 4-6 weeks upon healing of the surgical repair. The stent maybe used for an extended period but biological testing of the material used has shown a "slight irritation" in the 13 week biocompatibility implant test." This statement is acceptable**

The submission does not contain any information about cytotoxicity study (direct contact).

Vasant G. Malshet, Ph.D., DABT
Expert Toxicologist

DJA 00061

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

COVER SHEET MEMORANDUM

From: Reviewer Name Kozey Borkin

Subject: 510(k) Number K091135

To: The Record

Please list CTS decision code _____

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold). TH

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

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

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

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

Additional Product Codes:

Review: J. C. Callaway for Eric Mann MD ENTB 4/28/09
(Branch Chief) (Branch Code) (Date)

Final Review:
(Division Director) (Date)

DJA 00063

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

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

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

K091135

Date: April 27, 2009
To: The Record
From: Karen Baker

Office: ODE
Division: DOED

510(k) Holder: Boston Medical Products
Device Name: Rutter Supra Stomal Stents
Contact: Michael A. Warren
Phone: 508-898-9300 X228
Fax: 508-898-0488
Email: mwarren@bosmed.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Rutter Supra Stomas Stents into interstate commerce.

II. Administrative Requirements

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

III. **Device Description**: The Rutter Suprastomal Stent is a silicone stent system designed to provide support in the stenotic larynx and trachea. The stent is supplied as three components- the mail body of the silicone stent, a fenestrated plug and a non-fenestrated plug. The body of the stent has two tapered ends. The tapered end with the smaller diameter hole is designed to lie distally at the tracheostoma and may even slightly overlap the tracheostoma. The proximal end of the stent will accommodate the supplied plugs. The proximal end can be trimmed for custom stent length. The stent system is sterile for single patient use.

The fenestrated plug is the preferred plug as this allows for limited vocalization in some patients, and in the event of a tracheotomy occlusion or displacement, will allow for limited airflow thorough the stent. The non-fenestrated plug is supplied for use inpatients with a high risk of aspiration.

The stent is intended for long-term use. In most cases, the stent will be removed upon healing of the surgical repair, typically 4 to 6 weeks. However, from a material standpoint, the stent may be used on a longer-term basis at the discretion of the physician. The firm

DJA 00064

recommends that the maximum lifetime of the device be six months after insertion, after which time it should be replaced with a new device.

The device will be supplied in several sizes: size 6 mm to size 15 mm.

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

IV. Indications for Use: The Rutter Supra Stomas Stent is indicated for the prevention and treatment of laryngeal and tracheal stenosis.

V. Predicate Device Comparison: Lorenz Stent, K896667, indicated for

1. Chronic glottic and subglottic stenosis. Stenting after division of posterior cricoid lamina, with or without cartilage graft.

2. Combined chronic upper tracheal stenosis with or without laryngeal stenosis.

Subject device/predicate device comparative information:

	RUTTER SUPRA STOMAL STENT	LORENZ STENT
MANUFACTURER Inc	Boston Medical Products Inc.	Walter Lorenz Surgical
510(k) NO	K091135 (Pending)	K896667
DESIGN	Prefabricated Molded	Prefabricated Molded
MATERIAL	Silicone Elastomer	Teflon (PTFE)

DJA 00065

SIZES	10 Sizes- Ranging from 6mm-15mm	16 Sizes- Ranging from 6mm to 18mm
METHOD OF PLACEMENT	Sutures	Sutures
METHOD OF DEPLOYMENT	Not Applicable	Not Applicable
SUPPLIED STERILE	YES	YES

IV. **Labeling**: Sample labeling is provided including device description, indications for use, contraindications, precautions, and surgical techniques.

V. **Sterilization/Shelf Life/Reuse**: The devices are provided sterile, single use. See attached sterilization review sheet. – Perdum – FS

VI. **Biocompatibility**: (b)(4)Product Specs [redacted] elastomer. A master file of this material is on file with FDA. Vasant Malshet, PhD, DOED toxicologist was asked to comment on the material. His review is attached. Dr. Malshet requested the sponsor provide modified labeling informing the user that the material has been shown to be a mild irritant and also requested cytotoxicity test data.

IX. **Software**: There is no software in the device.

X. **Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**: There are no mechanical or electrical parts so there are no EMC, mechanical or thermal safety concerns.

XI. **Performance Testing – Bench**: No bench testing is provided.

XII. **Performance Testing – Animal**: No animal testing is provided.

XIII. **Performance Testing – Clinical**: No clinical testing is provided.

DJA 00066

XIV. Substantial Equivalence Discussion

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

Note: Number 3 is answered "no" as the material in the subject device is silicone and the material used in the predicate device is Teflon. See Section VI for details on the material and the toxicology reviewer comments.

XV. Deficiencies: The submission is placed on telephone hold pending receipt of the following biocompatibility information which was requested via e-mail on April 27, 2009.

(b) (4) [redacted] does not cause cytotoxicity, hemolysis, sensitization, acute systemic toxicity, intracutaneous toxicity, hemolysis, pyrogenicity, and mutation in bacterial cells. The Seven-day muscle implantation study did not show any irritation; however, the 13 week implantation study in the (b) (4) [redacted] showed slight irritation. Therefore, we recommend that you add a caution statement to the labeling stating, "The material in this device has been shown in biocompatibility studies to cause slight irritation".

In addition, since this device will be likely have patient contact for more than 30 days and the sterilization method used in the studies carried out in the master file is not the same, please provide cytotoxicity (direct contact method) study data on the final sterilized product. Alternatively you may provide an adequate scientific justification for not adding the caution statement and providing the cytotoxicity data.

A copy of the e-mail is attached.

XVI. Contact History

April 22, 2009, e-mail sent to sponsor requesting additional subject/predicate device comparison.
April 23, 2009, e-mail sent to sponsor requesting standards data report sheet.
April 27, 2007, e-mail sent to sponsor requesting the above biocompatibility/toxicology information.

DJA 00067

XVII. Recommendation: Telephone hold

Regulation Number:
Regulation Name: Prosthesis, Larynx (stents and keels)
Regulatory Class: Unclassified
Product Code: FWN

Reviewer — Date 4/27/09

Branch Chief — Date 4/28/09

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11135-1 Sterilization of Health Care Products- Ethylene Oxide- Part 1 : 2007

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 14-228	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: ISO 10993-7: 1995- Biological Evaluation of Medical Devices- Part 7: Sterilization Residuals: 1995

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics (301) 443-1090 EF

DJA 00069

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11135-1: 2007 Sterilization of Health Care Products- Ethylene Oxide Part 1: 2007

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
OPTION-Annex B	Conservative (b) (4) [redacted]	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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

DJA 00070

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-7:1995 Biological Evaluation of Medical Devices-(b) (4) [redacted]

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-76		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: ISO 11135-1 2007 (Revision to 1994 Standard)- Sterilization of Health Care Products : EtO Part 1

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

[2] Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

DJA 00071

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-7 Biological Evaluation of Medical Devices- (b) [redacted]

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.3	Allowable Limits	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4	(b) (4) [redacted]	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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

DJA 00072

Recognized Consensus Standards

Recognition List Number: 020 **Effective Date:** 09/09/2008

Part B: SUPPLEMENTARY INFORMATION

Recognition Number 14-228: AAMI / ANSI / ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices. (Sterility)

Date of Standard: 2007.

Addresses of Standards Organizations:

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI)
1110 N. GLEBE ROAD
SUITE 220
ARLINGTON, VA 22201-5762

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)
11 WEST 42ND STREET
NEW YORK, NY 10036

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)*
1, RUE DE VAREMBE
CASE POSTALE 56
CH 1211 GENEVA 20,
SWITZERLAND

CDRH Office and Division Associated with Recognized Standards:

ALL OFFICES AND DIVISIONS IN CDRH

Devices Affected:

All devices subjected to ethylene oxide sterilization

DJA 00073

Recognized Consensus Standards

Recognition List Number: 020 **Effective Date:** 09/09/2008

Part B: SUPPLEMENTARY INFORMATION

Recognition Number 14-76: AAMI / ANSI / ISO 10993-7:1995 (R) 2001, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals. (Sterility)

Date of Standard: 1995.

Addresses of Standards Organizations:

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI)
1110 N. GLEBE ROAD
SUITE 220
ARLINGTON, VA 22201-5762

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)
11 WEST 42ND STREET
NEW YORK, NY 10036

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)*
1, RUE DE VAREMBE
CASE POSTALE 56
CH 1211 GENEVA 20,
SWITZERLAND

CDRH Office and Division Associated with Recognized Standards:

ALL OFFICES AND DIVISIONS IN CDRH

Devices Affected:

All devices subjected to ethylene oxide sterilization

Processes Affected:

DJA 00074

Baker, Karen

From: Baker, Karen
Sent: Tuesday, April 28, 2009 10:42 AM
To: 'Mike Warren'
Subject: RE: k091135

Hi, Michael,

The remaining issue regarding this document has to do with the biocompatibility/toxicology review. I will need the following information to complete the review:

The [redacted] shows that the patient contacting material (b) (4) [redacted] (b) (4) [redacted] does not cause cytotoxicity, hemolysis, sensitization, acute systemic toxicity, intracutaneous toxicity, hemolysis, pyrogenicity, and mutation in bacterial cells. The Seven-day muscle implantation study did not show any irritation; however, the 13 week implantation study in the (b) (4) [redacted] showed slight irritation. Therefore, we recommend that you add a caution statement to the labeling stating, "The material in this device has been shown in biocompatibility studies to cause slight irritation".

In addition, since this device will be likely have patient contact for more than 30 days and the sterilization method used in the studies carried out in the master file is not the same, please provide cytotoxicity (direct contact method) study data on the final sterilized product. Alternatively you may provide an adequate scientific justification for not adding the caution statement and providing the cytotoxicity data.

I am placing the file on hold pending receipt of this information.

Karen

Karen Baker, MSN, RN
Expert Nurse Consultant
Ear, Nose and Throat Devices Branch
DOED/ODE/CDRH/FDA
240-276-4158
240-276-4156 (fax)
karen.baker@fda.hhs.gov

From: Mike Warren [mailto:mwarren@bosmed.com]
Sent: Thursday, April 23, 2009 1:54 PM
To: Baker, Karen
Subject: RE: k091135

Hello Karen:

Attached are the Consensus Standards Form.

Best regards,

DJA 00075

REVIEW OF TOXICOLOGY DATA

Date : April 28, 2009
From: : Vasant G. Malshet, Ph.D., DABT **Division/Branch:** DOED
To : Karen baker, RN **Division/Branch:** DOED
Trade Name: Rutter Supra stomal Stent
510(k) # : K091135
Applicant : **Boston Medical Products**

Checklist: Biocompatibility Evaluation of Medical Devices

Indications for Use: The Rutter Supra stomal Stent is intended for the prevention and treatment of laryngeal and tracheal stonosis.

Brief Device Description: The Rutter Supra Stomal Stent is manufactured of a soft but compliant silicone elastomer material that is suitable to support a stenotic trachea or larynx for the indications for use as defined. The stent is supplied as three components- the main body of the stent, a fennestrated plug and a nonfennestrated plug. The body of the stent has two tapered ends. The tapered end with the smaller diameter hole is designed to lie distally at the tracheostoma and may even slightly overlap the tracheostoma. The proximal end of the stent will accommodate one of the supplied plugs. The proximal end can be trimmed to length for exact fitting. The standard plug is fennestrated to allow a limited amount of air flow for voicing. The non-fennestrated plug is supplied for use in patients with a particular high risk of aspiration. Both the proximal plugged end of the stent and the distal end of the stent are rounded and smooth by design as to minimize the potential for granulation tissue formation. The plugs are pressed fit into place and do not require glueing or suturing to prevent displacement. The Rutter Supra Stomal Stent are available in a size range from 6mm-15mm in outside diameter. The lengths of the stents range from 80mm to 125mm depending on the size.

Component Materials:

The patient contacting material is (b) (4) [redacted]. The submission contains the permission (b) (4) [redacted] the master file.

DJA 00076

Component	Material(s)	Manufacturer	Patient Contact Potential	Previous Device Using Same Material with Similar Body Contact*
Device	Silicone	(b) (4) [redacted]	Yes	NA

*Description of how used in previous device (e.g., tissue contact, duration, etc.)

Type of Tissue Contact: (check one)

____ Surface device: skin
____ Surface device: mucosal membrane
__x__ Surface device: breached or compromised surfaces
____ External communicating device: blood path, indirect
____ External communicating device: tissue/bone/dentin
____ External communicating device: circulating blood
____ Implant device: tissue/bone
____ Implant device: blood

Duration of Contact: (check one)

____ < 24 hours
____ > 24 hours, but less than 30 days
__x__ > 30 days
____ potential for repeat exposure (If so, please explain)

Suggested Biocompatibility Testing for Devices (See Appendix B.)

Biocompatibility Testing Submitted: (See Table 2.)

Summary of Biocompatibility Data Submitted: (See Table 3.)

Table 3. Summary of Biocompatibility Data Submitted

Test	Results
	Company provided permission the access to the (b) (4) [redacted]

*Note: Where applicable, please verify whether polar and non-polar testing was performed.

Other Issues that Affect Biocompatibility:

Were test samples prepared with acceptable procedures using relevant extracting media? (For example, if the device was an *in situ* polymerized material, consider the necessity of testing monomers/oligomers, additives, intermediate reaction products, as well as fully polymerized material. If the

DJA 00077

test sample required extraction, consider whether extraction was accomplished properly with the appropriate number and type of extracts.)

When materials previously used in other devices are used together, consider the combined effects of these materials (i.e., synergistic effect, reactivity, etc.).

Table 2. Biocompatibility Testing Submitted

Biocompatibility Test	Recommended (will plan to add links to tests)	Provided	Need to provide
Cytotoxicity	x	x	
Sensitization	x	x	
Irritation or intracutaneous reactivity	x	x	
Acute systemic toxicity and material mediated pyrogenicity	x	x	
Sub-chronic toxicity			
Genotoxicity*			
Gene mutations in bacteria	x	x	
Gene mutations in mammalian cells			
Clastogenicity in mammalian cells			
Implantation	x	x	
Hemocompatibility			
Hemolysis	x	x	
Complement activation			
Thrombogenicity			
Chronic toxicity			
Carcinogenicity			
Reproductive/developmental			
Biodegradation			

*Per ISO 10993-3 genotoxicity testing should be performed using methods outlined in option 1.

DJA 00078

Appendix A: Material Certification - Biocompatibility Test Article

[redacted] (b) [redacted].

The (b) (4) [redacted] shows that the patient contacting material NuSil MED 4750 (b) (4) [redacted] does not cause cytotoxicity, hemolysis, sensitization, acute systemic toxicity, intracutaneous toxicity, hemolysis, pyrogenicity, and mutation in bacterial cells. Seven-day muscle implantation study did not show any irritation.

The 13 week implantation study in the (b) (4) [redacted] showed slight irritation. Therefore, I recommend that the sponsor add a caution statement to the labeling stating, "The material in this device has been shown in biocompatibility studies to cause slight irritation". Also since this device will be in patient contact for more than 30 days, the sterilization method used in the studies carried out in the master file are not the same, and just to make sure that nothing is leaching out of silicone during the manufacturing device, the company should provide cytotoxicity (direct contact method) study data on final sterilized product. Alternatively the company can provide an adequate scientific justification for not adding the caution statement and providing the cytotoxicity data.

Vasant G. Malshet, Ph.D., DABT
Expert Toxicologist

DJA 00079

T/R

Lab No. 96C 10435 00
REVISED REPORT

SUMMARY

The test article, Silicone Material, Identification No. CH-037 (Sample A), was implanted in muscle tissue of the rabbit. The muscle tissue was evaluated for evidence of irritation or toxicity in accordance with the guidelines of the current USP.

Implant samples and USP negative control strips were loaded into needles and sterilized by steam. Rabbits were implanted and were then euthanatized 13 weeks later. Muscle tissues were excised and the implant sites were examined macroscopically. A microscopic evaluation of representative implant sites from each rabbit was conducted to further define any tissue response.

Under the conditions of this study, the macroscopic reaction was not significant as compared to the USP negative control implant material. The implanted test article met the USP requirements. Microscopically, the test article was classified as a slight irritant as compared to the USP negative control article.

Study and Supervisory Personnel:

Chris Weeks, B.S.
Daphne Berry, B.S., LAT
Rajendra Sanathara, D.V.M.
America Salvador, B.S., ALAT
Jane Herriges, B.A., ALAT
Carlos Ramos
Abel Hernandez
David Vergil

Approved by:

Daphne Berry, B.S., LAT
Section Manager, Testing Services
Toxicology

9-9-97
Date Completed

Comments: This report has been revised to correct the study title. The conclusion is not affected. This revision is authorized by the signature above.

(b) (4)

[redacted]

1003U

DJA 00051

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

June 02, 2009

BOSTON MEDICAL PRODUCTS, INC.
117 FLANDERS RD.
WESTBOROUGH, MASSACHUSETTS 01581
UNITED STATES
ATTN: MICHAEL A. WARREN

510k Number: K091135

Product: RUTTER SUPRA STOMAL STENTS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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 (240)276-3150 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

DJA 00052

TO: Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, Maryland 20850

Major Resource Documents

510(k) NOTIFICATION

Boston Medical Products, Inc.
Rutter Supra-Stomal Stent

FROM: Boston Medical Products, Inc
Attn: Michael A. Warren
117 Flanders Road
Westborough, MA 01581
508-898-9300 Ext 228
MWarren@BOSMED.com

REFERENCE 510(k) No. (K091135)

K59

DJA 00053

K091135/S1

Boston
Medical Products

29 May 2009

FDA CDRH DMC
JUN 2 2009
Received

Karen Baker, MSN, RN
Expert Nurse Consultant
Ear, Nose and Throat Devices Branch
DOED/ODE/CDRH/FDA
9200 Corporate Blvd
Rockville, Maryland 20850

Dear Karen:

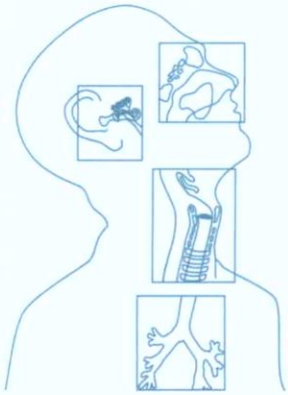
Attached is the updated hard copy of Indications for Use for the Rutter Supra-Stomal Stent (Ref 510K No K091135).

The change to The Lifetime of the Device section of the IFU has the added note of a "slight irritation" in the 13 week biocompatibility implant test. This is in response to your email of 28 May 2009 and the request of the FDA Toxicologist.

Please contact me if you have any further questions.

Best regards

Michael Warren



Boston Medical Products, Inc.
117 Flanders Road, Westborough, MA 01581 USA
Customer Service: 1-800-433-BMPI (2674)
Tel: 508-898-9300 • Fax: 508-898-2373
www.bosmed.com | www.trachs.com

DJA 00054

RUTTER SUPRASTOMAL STENT **N-RSS-A**
Instructions for Use

Product Codes

840006 - Size 6 Rutter Stent
840007 - Size 7 Rutter Stent
840008 - Size 8 Rutter Stent
840009 - Size 9 Rutter Stent
840010 - Size 10 Rutter Stent
840011 - Size 11 Rutter Stent
840012 - Size 12 Rutter Stent
840013 - Size 13 Rutter Stent
840014 - Size 14 Rutter Stent
840015 - Size 15 Rutter Stent

Description

The Rutter Suprastomal Stent is a silicone stent system designed to provide support in the stenotic larynx and trachea. The stent is supplied as three components - the main body of the silicone stent, a fenestrated plug and a non-fenestrated plug. The body of the stent has two tapered ends. The tapered end with the smaller diameter hole is designed to lie distally at the tracheostoma and may even slightly overlap the tracheostoma. The proximal end of the stent will accommodate the supplied plugs. The proximal end can be trimmed for custom stent length. The stent system is supplied sterile for single patient use.

Indications For Use

- To aid in the prevention and treatment of laryngeal and tracheal stenosis.

Lifetime of Device

The Rutter Suprastomal Stent is safe and effective for long-term use. In most cases, the stent will be removed between 4 to 6 weeks upon healing of the surgical repair. The stent may be used for an extended period but biological testing of the material used has shown a "slight irritation" in the 13 week biocompatibility implant test.

Contraindications

1. Care must be taken to smooth any shortened or modified intraluminal limb of the Rutter Stent prior to insertion.
2. The Rutter Stent must be used simultaneously with a tracheostomy tube.

Precautions

DJA 00055

1. Federal Law (USA) restricts this product to sale by or on the order of a physician.
2. Read instructions prior to use.
3. This product is for single patient use only

Insertion Technique - Surgical

1. The stent will usually be placed during open laryngotracheal airway surgery through an anterior cricoid split.
2. The stent is designed to be held in place by transfixation suture technique. Once the distal end of the stent is positioned to lie at the tracheostoma, a transfixation suture using 3.0 non-absorbable monofilament is placed. The suture should pass through the strap muscles on the left side of the neck, through the tracheal or cricoid wall, through the stent, and then exit the tracheal or cricoid cartilage, and pass through the strap muscles on the right side of the neck.
3. Clamps are applied to either end of the transfixation suture, but the suture is not yet tied.
4. The proximal end of the stent is now visualized by an assistant with a laryngoscope, and the stent removed from the wound and trimmed to the proper length such that the stent lies at level of the false cord. The stent can be trimmed using a Safe-T-Tube cutter or scissors.
5. Once satisfied with the proximal placement of the stent, the plug can be inserted. The fenestrated plug is the preferred plug as this allows for limited vocalization in some patients, and in the event of a tracheostomy occlusion or displacement, will allow for limited airflow through the stent. The non-fenestrated plug is supplied for use in patients with a high risk of aspiration. The plug is inserted into the proximal end such that is should not be displaced and should lie at the mid-epiglottic level. The smooth tapered design minimizes the risk of epiglottis granulation.
6. The airway may now be closed, including placement of cartilage grafts or anastomotic sutures. Once the strap muscles are re-opposed, the transfixation sutures may be tied. A 1-2 cm segment of angiocath is threaded over the left-hand end of the suture, and the suture then tied with a knot lying on the right side of the neck.
7. Approximately 20-30 throws of the knot are recommended to allow the suture to be easily found when the stent is to be removed.
8. The neck wound is then closed with the knot of the transfixation suture lying just beneath the skin.

Insertion Technique - Endoscopic

1. Occasionally it is desirable to endoscopically place a suprastomal stent. This may be challenging, and ideally should only be attempted in a patient with a thin neck, and with an assistant endoscopically guiding the surgeon.
2. The stent is designed as a transglottic suprastomal stent and therefore should only be used in patients with a tracheotomy.
3. The indications for consideration of an endoscopically placed stent include posterior cordotomy, endoscopic management of posterior glottic stenosis, and salvage

DJA 00056

stenting following laryngotracheal reconstruction.

4. The size of stent is determined by the anticipated size of the subglottis – for example a 4 year old child should accommodate a 5.0 endotracheal tube with an outer diameter of 6.8mm, therefore a 7mm stent would be selected (although a 6mm or 8mm stent could also be used). If the airway is stenotic, dilation may be required prior to stent insertion, and dilation with a balloon dilator 1mm greater in diameter than the size of the stent is ideal.
5. The stent is endoscopically inserted, with the tapered end (with the smaller lumen) distally, so that the end of the stent is just in contact with the tracheotomy tube. This may be established with either an endoscope placed through the tracheotomy to visualize the tip of the stent, or with a small Hopkins rod telescope placed inside the stent to visualize the tracheotomy tube.
6. The stent is then removed and trimmed to length so that the proximal cut end of the stent lies at false vocal cord level, while the distal end of the stent lies just at the stoma site.
7. The stent is reinserted into the airway.
8. Local anesthetic with epinephrine is infiltrated on either side of the neck approximately at the level of the cricoid cartilage.
9. A stab incision is made on the right side of the neck, and forceps used to bluntly dissect down to the mid point of the cricoid cartilage.
10. A long heavy Keith needle is selected, and a 3.0 non-absorbable monofilament suture (e.g. Prolene, 36 inch) threaded through it. It is useful to bend the tip of the needle so that it resembles the letter "J".
11. Then the needle is placed through the cricoid cartilage and into the lumen of the stent, where it is visualized by a Hopkin's rod endoscope placed into the lumen of the stent by the assistant surgeon. ***This is the most challenging part of the procedure, and may take several attempts.***
12. Once the Keith needle is visualized, it may then be passed through the stent, through the left side of the cricoid cartilages and into the soft tissues of the neck until it can be palpated subcutaneously. Care must be taken not to damage the great vessels, and the needle should pass anterior and medial to the great vessels.
13. A stab incision is placed over the needle tip, and the needle withdrawn from the neck.
14. The stent is now pedicled on the 3.0 suture which is passing through the stab incisions placed on either side of the neck.
15. Clamps are placed on the distal aspects of the transfixion suture, and keeping these taunt, the stent is removed from the airway, so that it is visible in the mouth, and the cap (fenestrated or unfenestrated) is then inserted.
16. Pulling on the sutures (and taking care not to twist them in the oral cavity), the stent is replaced in the airway.
17. Once satisfied with stent position, a forcep is placed through the right-sided stab incision, and bluntly tunneled (between skin and trachea) until it protrudes from the left neck incision.
18. The tip of the suture in the left neck is grasped in the forceps, and the suture withdrawn from the right side of the neck. This end of the suture then has a 1-2cm segment of 16G angiocath threaded over it, and the suture then tied with a knot

DJA 00057

lying on the right side of the neck. Approximately 20-30 throws of the knot are recommended to allow the suture to be easily found when the stent is to be removed.

19. The neck wounds are then closed with the knot of the transfixion suture lying just beneath the skin.
20. If difficulty is encountered with passing the Keith needle through the stent, it may be necessary to place a much larger transverse neck incision, and place the transfixion suture with the cricoid fully exposed.

Removal Technique

1. Removal of the stent is identical whether the stent has been placed during open airway reconstruction or endoscopic procedure.
2. Stent removal may be performed between 10 days and 6 months. The usual term of implantation is 4-6 weeks.
3. A small incision is made over the knot of the transfixation suture and dissected down to the angiocath.
4. The suture is cut and the suture and angiocath are removed from the neck.
5. An assistant meanwhile will remove the stent endoscopically from the larynx.

Warranty

Boston Medical Products, Inc. (BMPI) warrants that reasonable care has been used in the manufacturing of this device. As a result of biological differences in individuals, no product is 100% effective under all circumstances. Because of this fact and since we have no control over the conditions under which this device is used, diagnosis of the patient, methods of administration, or its handling after the device leaves our possession, BMPI does not warrant a good effect or against an ill effect following its use.

The physician must use this device based on his/her own medical training and experience. All medical professionals directly or indirectly using this device are responsible for its proper use.

BMPI shall not be liable for any incidental or consequential loss, damage or expense arising directly from the use of this product. BMPI will replace any device we determine to be defective at the time of shipment. BMPI may offer specific warranty periods for different products. Please call Customer Service for details. No representative of BMPI may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

Please direct any inquiries regarding this device to:

Boston Medical Products, Inc.
117 Flanders Road, Westborough, MA 01581 USA

DJA 00058

Tel: (508) 898-9300 Fax: (508) 898-2373

(b) (4)

[redacted]

DJA 00011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 05, 2009

BOSTON MEDICAL PRODUCTS, INC.
117 FLANDERS RD.
WESTBOROUGH, MASSACHUSETTS 01581
UNITED STATES
ATTN: MICHAEL A. WARREN

510k Number: K091135

Product: RUTTER SUPRA STOMAL STENTS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

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

Sincerely,

510(k) Staff

DJA 00012

K091135/S2

FDA CDRH DMC

AUG 0 5 2009

Received

TO: Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, Maryland 20850

Major Resource Documents

510(k) NOTIFICATION

Boston Medical Products, Inc.
Rutter Supra-Stomal Stent

K32

FROM: Boston Medical Products, Inc
Attn: Michael A. Warren
117 Flanders Road
Westborough, MA 01581
508-898-9300 Ext 228
MWarren@BOSMED.com

REFERENCE 510(k) NO. (K091135)

DJA 00013

Attachment B: GLP Compliance Notification Form

(b) (4)

[redacted]

DJA 00014

(b) (4) [redacted]

The following information is required for conducting non-clinical studies as outlined in the FDA Good Laboratory Practice regulations (21CFR Part 58) or EPA Good Laboratory Practices Standards (40 CFR Part 160)

A. Sponsor Identification and Test Request

Sponsor Name (Company Name): BOSTON MEDICAL PRODUCTS, INC

Sponsor Address: 117 FLANDERS RD
WESTBOROUGH, MA

Sponsor Representative: MICHAEL WARREN Sponsor PO: 90129

Test Description: (b) (4) [redacted] - CYTOTOXICITY TEST - DIRECT METHO

B. Test Article Identification:

1. Description: 840009 - RUTTER SUPRASTOMAL STENT

2. Batch/Code/Lot Identification (Circle One): SL-122 Expiration Date: 6\2014

3. Storage Conditions: ☒ Ambient ☐ 4°C Fridge ☐ -20°C Freezer ☐ -70°C Freezer ☐ Other: _____

4. Handling and Safety Precautions: NONE

5. Stability (As outlined in 21 CFR subpart F, Section 58.105):

☒ N/A

☐ Stability testing is in progress by the Sponsor.

☐ Stability Testing is complete and on file with the sponsor.

6. Test Article has been sterilized prior to submittal: ☒ Yes ☐ No ☐ N/A

Method of Sterilization: ETO

7. Disposition of Excess Test Material: ☒ Discard / Destroy ☐ Return to Sponsor

8. Disposition of Used Test Material: ☒ Discard / Destroy ☐ Return to Sponsor

(b) (4)

[redacted]

Sponsor	Boston Medical Products, Inc. 117 Flanders Road Westborough, MA 01581
Sponsor Representative	Michael Warren
Test Facility	(b) (4) [redacted]
Study Title	Direct Contact Cytotoxicity Testing (ISO Method)
Test Article Description	840009-Rutter Suprastomal Stent Lot #SL-122 exp 6/2014
Study Personnel	(b) (6) [redacted]

(b) (6)

[redacted]

(b) (4)

[redacted]

DJA 00015

DJA 00016

(b) (4)

[redacted]

1.0 Test Status

Study Initiation Date: 07Jul09
Test Initiation Date: 15Jul09
Test Completion Date: 16Jul09

2.0 Purpose of the Study

The direct contact test determines the toxicity of polymeric/elastomeric materials to cells *in vitro* when applied directly to the cell monolayer. The purpose of this procedure is to cover the steps required in performing the Direct Contact Assay.

3.0 Test System and Justification

The samples are applied to the L929 mammalian fibroblast, which was chosen for this study because it is a sensitive, dependable cell line that has historically been used to evaluate biomaterials for cytotoxic effects.

4.0 Sample Preparation

Test and control articles were tested as received by the sponsor. All related information can be found in the GLP Compliance Notification Form (Attachment B).

1. Obtained the sample from sample quarantine.
2. Prepared the 100 mm^2 sample in triplicate.
3. Recorded all data in worksheet on Attachment A of LAB-063.

Control Preparation

1. Prepared the negative control by cutting three (3) 1cm pieces of PFA tubing.
2. Prepared the positive control in triplicate by using autoclaved Latex by cutting three 100 mm^2 pieces.
3. Performed a blank control at the time of the extract plating. The original MEM will be removed from the cell culture plates, replaced with fresh MEM, and incubated with the remaining controls and samples as per section 10 of the protocol.

DJA 00017

(b) (4)

[redacted]

5.0 Methods

1. Grew and maintained the L929 cells in MEM at a density of approximately 2 x 10^5 cells per plate as per LAB-014.
2. Incubated the cell plates at 37 ± 1ºC in a humidified atmosphere containing 5 ± 1% CO_2 until a monolayer with greater than 80% confluency was obtained.
3. After monolayer is verified to 80% confluency, carefully removed the MEM from the monolayers.
4. Pipetted 0.8 mL of 10% MEM to each plate.
5. Prepared triplicate sample, negative and positive plates by adding the articles prepared per section 4.0 to the center of the plate.
6. For the blank control added 0.8 mL of 10% MEM to triplicate plates.
7. Incubated all plates for a minimum of twenty-four (24) hours + 1 hour at 37 ± 1 °C in a humidified atmosphere containing 5 ± 1% CO_2 in air.
8. After completion of the incubation, the plates were scored according to the USP Grading Scale.

Table 1

Grade	Reactivity	Description of Reactivity Zone
0	None	No detectable zone around or under the specimen
1	Slight	Some malformed or degenerated cells under the specimen
2	Mild	Zone limited to area under the specimen
3	Moderate	Zone extends 0.5 to 1.0 cm beyond the specimen
4	Severe	Zone extends greater than 1.0 cm beyond the specimen

6.0 Deviations and Amendments

No deviations or amendments occurred during this study.

(b) (4) [redacted]

DJA 00018

7.0 Discussion

N/A

8.0 Results

Sample: 840009-Rutter Suprastomal Stent Lot #SL-122 exp 6/2014	Specifications per USP 32<87>	Grade Results		
		Plate 1	Plate 2	Plate 3
	Sample: ≤ 2	0	0	0
	Blank: 0	0	0	0
	Negative: 0	0	0	0
	Positive: ≥3	4	4	4

Culture Medium: 10% MEM
Cell Line: L929 Mouse Connective Tissue

9.0 Statistical Methods

No statistical methods were employed in this study.

10.0 Conclusion

The samples tested meet the ISO requirements of the test with a Grade of 0, (passing criteria: a grade of not more than 2).
The controls tested meet the ISO requirements of the test (positive exhibiting a grade of at least 3 and the negative and blank exhibiting a grade of 0).

11.0 Records

All raw data, documentation, protocols and final reports generated for this study will be retained in [redacted] (b) (4) for 5 years following the study initiation date.

12.0 Quality Assurance

Quality Assurance certifies that the article described in this test report was tested under the Regulations described in 21 CFR Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies. The records and reports will be maintained at (b) (4) [redacted] for not less than 5 years.

(b) (4)

[redacted]

This report has been audited by [redacted] (b) (4) [redacted] Department and has been found to accurately describe the methods and procedures used in the study. The reported results accurately reflect the raw data of the study.

The following inspections of this study were performed by (b) (4) [redacted]. Findings were reported to the study director and management on the Inspection Dates reported below.

Inspection Date	Inspection Phase	Findings
16 July 09	Sample Grading	Satisfactory
28 July 09	Final Report	Satisfactory

(b) (6)

[redacted]

13.0 References

- LAB-014 Cytotoxicity Cell Line Maintenance Program
- LAB-063 Cytotoxicity testing (Preparation, Documentation, and Reporting)
- (b) (4) [redacted] Direct Contact Cytotoxicity Testing (ISO Method)
- ANSI/ AAMI/ ISO 10993-5: Biological Evaluation of Medical Device Part 5: Tests *In-vitro* Cytotoxicity
- ANSI/ AAMI/ ISO 10993-12: Biological Evaluation of Medical Devices Part 12: Sample Preparation and Reference Materials
- USP (Current Edition)

14.0 Attachments

Attachment A: Controlled Copy of SPN Protocol
Attachment B: GLP Compliance Notification Form

DJA 00020

Attachment A: Controlled Copy of SPN Protocol

(b) (4)

[redacted]

DJA 00021

(b) (4)

[redacted]

Sponsor:

Boston Medical Products, Inc
117 Flanders Road
Westborough, MA 01581

Test Facility:

(b) (4)

[redacted]

Study Title:

Direct Contact Cytotoxicity Testing (ISO Method)

Test Article Description:

840009-Rutter Suprastomal Stent Lot # SL-122 exp 6/2014

(b) (6)

[redacted]

DJA 00022

1 Purpose of the Study

The direct contact test determines the toxicity of polymeric/elastomeric materials to cells *in vitro* when applied directly to the cell monolayer. The purpose of this procedure is to cover the steps required in performing the Direct Contact Assay.

2 Test System and Justification

The samples are applied to the L929 mammalian fibroblast, which was chosen for this study because it is a sensitive, dependable cell line that has historically been used to evaluate biomaterials for cytotoxic effects.

3 Test Summary

Test article(s) are directly placed on L929 cell monolayers within 35 X 10mm culture plates. Negative and positive controls are evaluated simultaneously. All plates are incubated at 37 ±1°C in a humidified atmosphere containing 5 ± 1% CO_2 for twenty-four (24) hours + 1 hour. Upon completion of the incubation, the plates are then microscopically graded for cytotoxicity per USP criteria.

4 Test Article

The test material and all information regarding its identification, stability, storage and disposition will be provided by the client and detailed on the GLP Compliance Notification Form. A GLP Compliance Notification is to be supplied by the sponsor each time a test article is submitted for testing per this study protocol.

5 Control Material

Standard positive (Natural Latex Rubber) and negative (PFA Tubing or USP Negative Bioreaction Reference Standard) controls are tested with every test article evaluation.

6 Definitions

MEM - Minimum Essential Medium

7 Materials Required

- Culture: L929 Mouse Connective Tissue (ATCC #CCL-1)
- Culture Vessel: 75 cm^2 flask containing a confluent monolayer of cells
- Growth/ Extraction Medium: 10% Sterile MEM

Effective On
JUL 07 2009
Master Copy is Red

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DJA 00023

- Hank's Balanced Salt Solution
- 0.25% Trypsin
- Sterile 35 x 15 mm cell culture petri plates
- Sterile, depyrogenated extraction vessel
- Sterile utensils
- Sterile (glass, disposable) pipettes: 1.0 and 10.0 mL
- Sterile disposable glass tubes
- USP Negative Bioreaction Reference Standard (Negative Control USP Plastic) or Teflon PFA tubing
- Natural Latex Rubber Positive Control

8 Equipment

- 37°C ± 1°C, 5±1% CO_2, humidified incubator
- Olympus CK2 Inverted Microscope
- Automatic pipettor equipped with filter
- Class 100 Laminar Flow Hood

9 Preparation

9.1 Sample Preparation

1. Obtain sample from sample quarantine.
2. Prepare the test article as to not have less than 100 mm^2 in surface area.
3. Prepare the test article in triplicate.
4. Record all data in Attachment A of LAB-014.

9.2 Control Preparation

1. Prepare the negative control by cutting three (3) 1cm pieces of PFA tubing material or 100 mm^2 in surface area of USP plastic.
2. Prepare the positive control in triplicate by using autoclaved Latex by cutting three 100 mm^2 pieces.
3. Perform a blank control at the time of the extract plating. The original MEM will be removed from the cell culture plates, replaced with fresh MEM, and incubated with the remaining controls and samples as per section 10.

DJA 00024

10 Test Method

1. Grow and maintain the L929 cells in MEM at a density of approximately 2 x 10^5 cells per plate as per LAB-014.
2. Incubate the cell plates at 37 ± 1°C in a humidified atmosphere containing 5 ± 1% CO_2 until a monolayer with greater than 80% confluency is obtained (not less than 24 hours).
3. After monolayer is verified to 80% confluency, carefully remove the MEM from the monolayers.
4. Pipette 0.8 mL of 10% MEM to each plate.
5. Prepare triplicate sample, negative and positive plates by adding the articles to the center of the plate.
6. For the blank control just add 0.8 mL of 10% MEM to triplicate plates.
7. Incubate all plates for a minimum of twenty-four (24) hours + 1 hour at 37 ± 1 °C in a humidified atmosphere containing 5 ± 1% CO_2 in air.
8. Upon completion of the incubation, score the plates according to the USP Grading Scale.

Table 1

Grade	Reactivity	Description of Reactivity Zone
0	None	No detectable zone around or under the specimen
1	Slight	Some malformed or degenerated cells under the specimen
2	Mild	Zone limited to area under the specimen
3	Moderate	Zone extends 0.5 to 1.0 cm beyond the specimen
4	Severe	Zone extends greater than 1.0 cm beyond the specimen

11 Proposed Statistical Methods

N/A

CONTROLLED COPY

DJA 00025

12 Acceptance Criteria

1. The sample meets the requirements of the test if none of the cell monolayer exposed to the sample shows greater than a mild reactivity (Grade 2).
2. The Positive control must exhibit a grade of ≥ three (3).
3. The Negative control must exhibit a grade of zero (0).
4. The Blank control must exhibit a grade of zero (0).
5. The triplicate plates for each sample must not be more than one (1) grade apart, or the test is invalid and must be repeated.

13 Report

The report will contain a summary of the methods employed, results, conclusions and abnormal observations, if noted.

14 Records

All raw data, documentation, protocols and final reports generated by this study are retained in the archives at [redacted], (b) for a period of five (5) years following study initiation.

15 Quality Assurance

1. The quality assurance unit will conduct inspections during a minimum of one of the following and of the final report:
   a. Sample preparation and extraction
   b. Sample grading
2. A signed Quality Assurance statement will be included with the final study report submitted to the sponsor. This study will be conducted according to the Good Laboratory Practice Regulations of Title: 21, CFR: Part 58.

16 References

- LAB-014 Cytotoxicity Cell Line Maintenance Program
- LAB-063 Cytotoxicity testing (Preparation, Documentation, and Reporting)
- (b) (4) [redacted] Direct Contact Cytotoxicity Testing (ISO Method)
- ANSI/ AAMI/ ISO 10993-5: Biological Evaluation of Medical Device Part 5: Tests *In-vitro* Cytotoxicity

DJA 00026

- ANSI/ AAMI/ ISO 10993-12: Biological Evaluation of Medical Devices Part 12: Sample Preparation and Reference Materials
- USP (Current Edition)

17 Proposed Dates

Estimated starting and completion dates will be provided to the sponsor upon receipt of the test material(s) and approved protocol(s).

18 Attachments

N/A

(b) (6)

[redacted]

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Attachment B: GLP Compliance Notification Form

(b) (4) [redacted]

DJA 00028

(b) (4) [redacted]

The following information is required for conducting non-clinical studies as outlined in the FDA Good Laboratory Practice regulations (21CFR Part 58) or EPA Good Laboratory Practices Standards (40 CFR Part 160)

A. Sponsor Identification and Test Request

Sponsor Name (Company Name): BOSTON MEDICAL PRODUCTS, INC

Sponsor Address: 117 FLANDERS RD
WESTBOROUGH, MA

Sponsor Representative: MICHAEL WARREN Sponsor PO: 90129

Test Description: (b) (4) [redacted] - CYTOTOXICITY TEST - DIRECT METHOD

B. Test Article Identification:

1. Description: 840009 - RUTTER SUPRASTOMAL STENT

2. Batch/Code/Lot Identification (Circle One): SL-122 Expiration Date: 6/2014

3. Storage Conditions: ☒ Ambient ☐ 4°C Fridge ☐ -20°C Freezer ☐ -70°C Freezer ☐ Other: _____

4. Handling and Safety Precautions: NONE

5. Stability (As outlined in 21 CFR subpart F, Section 58.105):

☒ N/A

☐ Stability testing is in progress by the Sponsor.

☐ Stability Testing is complete and on file with the sponsor.

6. Test Article has been sterilized prior to submittal: ☒ Yes ☐ No ☐ N/A

Method of Sterilization: ETO

7. Disposition of Excess Test Material: ☒ Discard / Destroy ☐ Return to Sponsor

8. Disposition of Used Test Material: ☒ Discard / Destroy ☐ Return to Sponsor

(b) (4)

[redacted]

DJA 00029

Sponsor	Boston Medical Products, Inc. 117 Flanders Road Westborough, MA 01581
Sponsor Representative	Michael Warren
Test Facility	(b) (4) [redacted]
Study Title	Direct Contact Cytotoxicity Testing (ISO Method)
Test Article Description	840009-Rutter Suprastomal Stent Lot #SL-122 exp 6/2014
Study Personnel	(b) (6) [redacted]

(b) (6)

[redacted]

(b) (4)

[redacted]

DJA 00030

1.0 Test Status

Study Initiation Date:	07Jul09
Test Initiation Date:	15Jul09
Test Completion Date:	16Jul09

2.0 Purpose of the Study

The direct contact test determines the toxicity of polymeric/elastomeric materials to cells *in vitro* when applied directly to the cell monolayer. The purpose of this procedure is to cover the steps required in performing the Direct Contact Assay.

3.0 Test System and Justification

The samples are applied to the L929 mammalian fibroblast, which was chosen for this study because it is a sensitive, dependable cell line that has historically been used to evaluate biomaterials for cytotoxic effects.

4.0 Sample Preparation

Test and control articles were tested as received by the sponsor. All related information can be found in the GLP Compliance Notification Form (Attachment B).

1. Obtained the sample from sample quarantine.
2. Prepared the 100 mm^2 sample in triplicate.
3. Recorded all data in worksheet on Attachment A of LAB-063.

Control Preparation

1. Prepared the negative control by cutting three (3) 1cm pieces of PFA tubing.
2. Prepared the positive control in triplicate by using autoclaved Latex by cutting three 100 mm^2 pieces.
3. Performed a blank control at the time of the extract plating. The original MEM will be removed from the cell culture plates, replaced with fresh MEM, and incubated with the remaining controls and samples as per section 10 of the protocol.

DJA 00031

5.0 Methods

1. Grew and maintained the L929 cells in MEM at a density of approximately 2 x 10^5 cells per plate as per LAB-014.
2. Incubated the cell plates at 37 ± 1°C in a humidified atmosphere containing 5 ± 1% CO_2 until a monolayer with greater than 80% confluency was obtained.
3. After monolayer is verified to 80% confluency, carefully removed the MEM from the monolayers.
4. Pipetted 0.8 mL of 10% MEM to each plate.
5. Prepared triplicate sample, negative and positive plates by adding the articles prepared per section 4.0 to the center of the plate.
6. For the blank control added 0.8 mL of 10% MEM to triplicate plates.
7. Incubated all plates for a minimum of twenty-four (24) hours ± 1 hour at 37 ± 1 °C in a humidified atmosphere containing 5 ± 1% CO_2 in air.
8. After completion of the incubation, the plates were scored according to the USP Grading Scale.

Table 1

Grade	Reactivity	Description of Reactivity Zone
0	None	No detectable zone around or under the specimen
1	Slight	Some malformed or degenerated cells under the specimen
2	Mild	Zone limited to area under the specimen
3	Moderate	Zone extends 0.5 to 1.0 cm beyond the specimen
4	Severe	Zone extends greater than 1.0 cm beyond the specimen

6.0 Deviations and Amendments

No deviations or amendments occurred during this study.

DJA 00032

7.0 Discussion

N/A

8.0 Results

Sample: 840009-Rutter Suprastomal Stent Lot #SL-122 exp 6/2014	Specifications per USP 32<87>	Grade Results		
		Plate 1	Plate 2	Plate 3
	Sample: ≤ 2	0	0	0
	Blank: 0	0	0	0
	Negative: 0	0	0	0
	Positive: ≥3	4	4	4

Culture Medium: 10% MEM
Cell Line: L929 Mouse Connective Tissue

9.0 Statistical Methods

No statistical methods were employed in this study.

10.0 Conclusion

The samples tested meet the ISO requirements of the test with a Grade of 0, (passing criteria: a grade of not more than 2).
The controls tested meet the ISO requirements of the test (positive exhibiting a grade of at least 3 and the negative and blank exhibiting a grade of 0).

11.0 Records

All raw data, documentation, protocols and final reports generated for this study will be retained in [redacted], (b) [redacted] for 5 years following the study initiation date.

12.0 Quality Assurance

Quality Assurance certifies that the article described in this test report was tested under the Regulations described in 21 CFR Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies. The records and reports will be maintained at [redacted] (b) not less than 5 years.

DJA 00033

This report has been audited by [redacted] (b) (4) [redacted] Department and has been found to accurately describe the methods and procedures used in the study. The reported results accurately reflect the raw data of the study.

The following inspections of this study were performed by (b) (6) [redacted]. Findings were reported to the study director and management on the Inspection Dates reported below.

(b) (4) [redacted]

13.0 References

- LAB-014 Cytotoxicity Cell Line Maintenance Program
- LAB-063 Cytotoxicity testing (Preparation, Documentation, and Reporting)
- (b) (4) [redacted], Direct Contact Cytotoxicity Testing (ISO Method)
- ANSI/ AAMI/ ISO 10993-5: Biological Evaluation of Medical Device Part 5: Tests *In-vitro* Cytotoxicity
- ANSI/ AAMI/ ISO 10993-12: Biological Evaluation of Medical Devices Part 12: Sample Preparation and Reference Materials
- USP (Current Edition)

14.0 Attachments

Attachment A: Controlled Copy of SPN Protocol
Attachment B: GLP Compliance Notification Form

DJA 00034

Attachment A: Controlled Copy of SPN Protocol

(b) (4)

[redacted]

DJA 00035

(b)(4)Product Specs

[redacted]

Sponsor:

Boston Medical Products, Inc
117 Flanders Road
Westborough, MA 01581

Test Facility:

MicroTest Laboratories, Inc.
104 Gold Street
Agawam, MA 01001

Study Title:

Direct Contact Cytotoxicity Testing (ISO Method)

Test Article Description:

840009-Rutter Suprastomal Stent Lot # SL-122 exp 6/2014

(b) (4)

[redacted]

DJA 00036

1 Purpose of the Study

The direct contact test determines the toxicity of polymeric/elastomeric materials to cells *in vitro* when applied directly to the cell monolayer. The purpose of this procedure is to cover the steps required in performing the Direct Contact Assay.

2 Test System and Justification

The samples are applied to the L929 mammalian fibroblast, which was chosen for this study because it is a sensitive, dependable cell line that has historically been used to evaluate biomaterials for cytotoxic effects.

3 Test Summary

Test article(s) are directly placed on L929 cell monolayers within 35 X 10mm culture plates. Negative and positive controls are evaluated simultaneously. All plates are incubated at 37 ±1°C in a humidified atmosphere containing 5 ± 1% CO_2 for twenty-four (24) hours + 1 hour. Upon completion of the incubation, the plates are then microscopically graded for cytotoxicity per USP criteria.

4 Test Article

The test material and all information regarding its identification, stability, storage and disposition will be provided by the client and detailed on the GLP Compliance Notification Form. A GLP Compliance Notification is to be supplied by the sponsor each time a test article is submitted for testing per this study protocol.

5 Control Material

Standard positive (Natural Latex Rubber) and negative (PFA Tubing or USP Negative Bioreaction Reference Standard) controls are tested with every test article evaluation.

6 Definitions

MEM - Minimum Essential Medium

7 Materials Required

- Culture: L929 Mouse Connective Tissue (ATCC #CCL-1)
- Culture Vessel: 75 cm^2 flask containing a confluent monolayer of cells
- Growth/ Extraction Medium: 10% Sterile MEM

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DJA 00037

- Hank's Balanced Salt Solution
- 0.25% Trypsin
- Sterile 35 x 15 mm cell culture petri plates
- Sterile, depyrogenated extraction vessel
- Sterile utensils
- Sterile (glass, disposable) pipettes: 1.0 and 10.0 mL
- Sterile disposable glass tubes
- USP Negative Bioreaction Reference Standard (Negative Control USP Plastic) or Teflon PFA tubing
- Natural Latex Rubber Positive Control

8 Equipment

- 37°C ± 1°C, 5±1% CO_2, humidified incubator
- Olympus CK2 Inverted Microscope
- Automatic pipettor equipped with filter
- Class 100 Laminar Flow Hood

9 Preparation

9.1 Sample Preparation

1. Obtain sample from sample quarantine.
2. Prepare the test article as to not have less than 100 mm^2 in surface area.
3. Prepare the test article in triplicate.
4. Record all data in Attachment A of LAB-014.

9.2 Control Preparation

1. Prepare the negative control by cutting three (3) 1cm pieces of PFA tubing material or 100 mm^2 in surface area of USP plastic.
2. Prepare the positive control in triplicate by using autoclaved Latex by cutting three 100 mm^2 pieces.
3. Perform a blank control at the time of the extract plating. The original MEM will be removed from the cell culture plates, replaced with fresh MEM, and incubated with the remaining controls and samples as per section 10.

DJA 00038

10 Test Method

1. Grow and maintain the L929 cells in MEM at a density of approximately 2 x 10^5 cells per plate as per LAB-014.
2. Incubate the cell plates at 37 ± 1°C in a humidified atmosphere containing 5 ± 1% CO_2 until a monolayer with greater than 80% confluency is obtained (not less than 24 hours).
3. After monolayer is verified to 80% confluency, carefully remove the MEM from the monolayers.
4. Pipette 0.8 mL of 10% MEM to each plate.
5. Prepare triplicate sample, negative and positive plates by adding the articles to the center of the plate.
6. For the blank control just add 0.8 mL of 10% MEM to triplicate plates.
7. Incubate all plates for a minimum of twenty-four (24) hours + 1 hour at 37 ± 1°C in a humidified atmosphere containing 5 ± 1% CO_2 in air.
8. Upon completion of the incubation, score the plates according to the USP Grading Scale.

Table 1

Grade	Reactivity	Description of Reactivity Zone
0	None	No detectable zone around or under the specimen
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2	Mild	Zone limited to area under the specimen
3	Moderate	Zone extends 0.5 to 1.0 cm beyond the specimen
4	Severe	Zone extends greater than 1.0 cm beyond the specimen

11 Proposed Statistical Methods

N/A

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DJA 00039

12 Acceptance Criteria

1. The sample meets the requirements of the test if none of the cell monolayer exposed to the sample shows greater than a mild reactivity (Grade 2).
2. The Positive control must exhibit a grade of ≥ three (3).
3. The Negative control must exhibit a grade of zero (0).
4. The Blank control must exhibit a grade of zero (0).
5. The triplicate plates for each sample must not be more than one (1) grade apart, or the test is invalid and must be repeated.

13 Report

The report will contain a summary of the methods employed, results, conclusions and abnormal observations, if noted.

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1. The quality assurance unit will conduct inspections during a minimum of one of the following and of the final report:
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- (b) (4) [redacted] Direct Contact Cytotoxicity Testing (ISO Method)
- ANSI/ AAMI/ ISO 10993-5: Biological Evaluation of Medical Device Part 5: Tests *In-vitro* Cytotoxicity

DJA 00040

- ANSI/ AAMI/ ISO 10993-12: Biological Evaluation of Medical Devices Part 12: Sample Preparation and Reference Materials
- USP (Current Edition)

17 Proposed Dates

Estimated starting and completion dates will be provided to the sponsor upon receipt of the test material(s) and approved protocol(s).

18 Attachments

N/A

19 Sponsor Approval of Study Protocol

7/7/09

Date

Michael Warren
Boston Medical Products, Inc
117 Flanders Road
Westborough, MA 01581

(b) (6)

[redacted]