Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

Special 510(k) Summary: Device Modification to the Asnis III Cannulated Screw System

K024060
page 1 of 1

DEC 2 0 2002

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	December 6, 2002

Device Identification

Proprietary Name:	Asnis III Cannulated Screw System
Common Name:	Bone Screw
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030

This Special 510(k) submission is intended to address design modifications to the Asnis III Cannulated Screw System. Additional lengths have been added to the 8.0 mm diameter screws. The core thread diameter of the 6.5 mm diameter screws has been modified. The material, intended use, packaging and sterilization of the subject devices are identical to those of predicate devices.

Intended Use

The intended use of the modified devices, as described in its labeling, has not changed as a result of this modification. These devices are intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

Statement of Technological Comparison

Mechanical testing and analysis demonstrates comparable properties of the subject to the predicate device.

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Ms. Karen Ariemma
Regulatory Affairs Specialist
Stryker Howmedica Osteonics Corp.
59 Route 17 South
Allendale, New Jersey 07401-1677

Re: K024060
Trade Name: Asnis III Cannulated Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HWC
Dated: December 6, 2002
Received: December 9, 2002

Dear Ms. Ariemma:

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

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

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

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

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

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

Sincerely yours,

Miriam C. Provost

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

Enclosure

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

510(k) Number (if known): K024060

Device Name: Asnis III Cannulated Screw System

Indications for Use

The Asnis III Cannulated Screw System intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K024060

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Ms. Karen Ariemma
Regulatory Affairs Specialist
Stryker Howmedica Osteonics Corp.
59 Route 17 South
Allendale, New Jersey 07401-1677

Re: K024060
Trade Name: Asnis III Cannulated Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

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Sincerely yours,

Miriam C. Provost

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

Enclosure

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

510(k) Number (if known): K024060

Device Name: Asnis III Cannulated Screw System

Indications for Use

The Asnis III Cannulated Screw System intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K024060

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

December 09, 2002

HOWMEDICA OSTEONICS CORP.
59 ROUTE 17
ALLENDALE, NJ 07401
ATTN: KAREN ARIEMMA

510(k) Number: K024060
Received: 09-DEC-2002
Product: MODIFICATION TO ASNIS III CANNULATED SCREW SYSTEM

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

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

Sincerely yours,

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

0015

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

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K024060

stryker®
Howmedica
OSTEONICS

59 Route 17 South
Allendale, NJ 07401

Via Federal Express

December 6, 2002

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

FDA/CDRH/ODE/PMG
2002 DEC -9 P 1:58
RECEIVED

Re: Special 510(k) Notification
Device Modification to the Asnis III Cannulated Screw System

Ladies and Gentlemen:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), Subpart E, this 510(k) Premarket Notification is being submitted prior to the date when Howmedica Osteonics Corp. proposes to introduce into interstate commerce, for commercial distribution, modifications to the Asnis III Cannulated Screw System.

This submission contains methods, data, and analysis of these data which Howmedica Osteonics Corp. considers "Trade Secret" and commercially privileged and confidential to Howmedica Osteonics Corp. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with the Freedom of Information (FOI) Act.

To the best of Howmedica Osteonics' knowledge and belief, all data and information contained herein are truthful and accurate, and no facts material to the subject determination have been omitted. Although the Asnis III Cannulated Screw System is substantially equivalent to the predicate device within the meaning of Section 513(i)(1)(A) of the Federal Food, Drug and Cosmetic Act, nothing in this submission in any way reflects upon the completely unrelated federal patent law "doctrine of equivalents'.

The Indications for Use Form and the Truthful and Accuracy Statement immediately follow this letter.

Your early attention to this submission is appreciated. Please refer any questions regarding this submission to Karen Ariemma at (201) 831-5718.

Sincerely,
Howmedica Osteonics Corp.

William J. Cymbaluk
Vice President, Quality Assurance/ Regulatory Affairs/ Clinical Research

0016

SKH1
OR
II

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

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Premarket Notification
Truthful and Accurate Statement
[as required by 21 CFR §807.87j)]

I certify that, in my capacity as Vice President, Quality Assurance/ Regulatory Affairs/Clinical Research of Howmedica Osteonics Corp., 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.

William J. Cymbaluk

12/6/02
Date

Premarket Notification [510(k)] Number:

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

SPECIAL 510(k) PREMARKET NOTIFICATION:

DEVICE MODIFICATION TO THE ASNIS III

CANNULATED SCREW SYSTEM

Howmedica Osteonics Corp.

59 Route 17

Allendale, New Jersey 07401-1677

December 6, 2002

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

510(k) Number (if known): K024060

Device Name: Asnis III Cannulated Screw System

Indications for Use

The Asnis III Cannulated Screw System intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

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Special 510(k) Summary: Device Modification to the Asnis III Cannulated Screw System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	December 6, 2002

Device Identification

Proprietary Name:	Asnis III Cannulated Screw System
Common Name:	Bone Screw
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030

This Special 510(k) submission is intended to address design modifications to the Asnis III Cannulated Screw System. Additional lengths have been added to the 8.0 mm diameter screws. The core thread diameter of the 6.5 mm diameter screws has been modified. The material, intended use, packaging and sterilization of the subject devices are identical to those of predicate devices.

Intended Use

The intended use of the modified devices, as described in its labeling, has not changed as a result of this modification. These devices are intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

Statement of Technological Comparison

Mechanical testing and analysis demonstrates comparable properties of the subject to the predicate device.

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

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

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SECTION I

ADMINISTRATIVE INFORMATION

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

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Manufacturer Identification

Name and Address of the Sponsor of the 510(k) Submission

Howmedica Osteonics Corp.

59 Route 17

Allendale, NJ 07401-1677

Establishment Registration Number: 2243265

Name and Address of the Manufacturers of the Device

Stryker Trauma AG

Bohnackerweg 1

CH-2545 Selzach, Switzerland

Establishment Registration Number: 8031020

Name and Address of the Distributor of the Device

Howmedica Osteonics Corp.

300 Commerce Court

Mahwah, NJ 07430

Establishment Registration Number: 2249697

Contact Person

Karen Ariemma

Regulatory Affairs Specialist

Phone (201) 831-5718

Fax (201) 831-6038

e-mail: kariemma@howost.com

0023

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

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SECTION II

DEVICE IDENTIFICATION

0024

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

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Device Identification

Proprietary Name:	Asnis III Cannulated Screw System
Common Name:	Bone Screw
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030
Proposed Regulatory Class:	Class II
Device Panel/Product Code:	HWC, Screw, Fixation, Bone

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

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SECTION III

DEVICE DESCRIPTIVE INFORMATION

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

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Introduction

This Special 510(k) submission is intended to address design modifications to the Asnis III Cannulated Screw System. Additional lengths have been added to the 8.0 mm diameter screws and the core thread diameter of the 6.5 mm diameter screws has been increased. The material, intended use, packaging and sterilization of the subject device are identical to those of predicate device.

Device History and Description

The predicate Asnis III Cannulated Screw System was determined substantially equivalent via 510(k) K000080. The Asnis III Cannulated Screw System consists of self-tapping cannulated screws and the associated washers. All devices in the system are provided sterile and non-sterile. The Asnis III Cannulated Screws are available fully or partially threaded and in 4.0, 5.0, 6.5, and 8.0 mm thread diameters. All screws are self-drilling and self-tapping. The Asnis III Cannulated Screws are fabricated from either titanium alloy or stainless steel.

Intended Use

The intended use of the modified devices, as described in its labeling, has not changed as a result of this modification.

Indications

These devices are intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

Description of Device Modification

<u>8.0 mm diameter Asnis III Cannulated Screws.</u>

The modification to the predicate stainless steel 8.0 mm diameter Partially Threaded Screws is the addition of longer lengths. Lengths ranging from 135 – 180 mm in 5 mm increments will be added to the system. With the exception of the additional length, the design of the subject device is identical to that of predicate device.

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

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6.5 mm diameter Asnis III Cannulated Screws

The modification of the predicate 6.5 mm diameter Asnis III Cannulated Screws, Partially and Fully Threaded, in both titanium alloy and stainless steel, is the increase in core thread diameter from 4.5 mm to 4.75 mm. With the exception of the core thread diameter, the design of the subject device is identical to that of predicate device.

Materials

The subject components are fabricated from stainless steel per ASTM 138, ASTM 1314 or DIN 17443 and titanium alloy per ASTM F 136. These materials have a long and successful history of use in orthopaedic implant surgery.

Labeling

The labels for the subject Asnis III Cannulated Screws are presented in Appendix B-1. The package insert is presented in Appendix B-2.

Design Control

Howmedica Osteonics has undertaken analysis of the design modification to Asnis III Cannulated Screws in order to determine what consequences/effects the additional lengths of 8.0 mm diameter screws and increased root diameter of 6.5 mm screws may impose on the safety and effectiveness of the device.

8.0 mm diameter screws

Because the screw will be held within four cortical walls the biomechanical behavior is dependent on torsional and cutting properties only. The bending forces on the screw are close to zero due to the fact that in the middle section of the screw, which is not supported by a cortical buttress, no force will be applied.

Biomechanical testing was performed comparing 60 mm length predicate screws to the subject 180 mm length screws. Insertion torque, strip-out torque shear-off torque, breaking angle and pull-out strength were determined. Insertion torque testing was performed per ASTM F117, "Test Method for Driving Torque of Medical Bone Screws". Pull-out testing was performed per ATSM F1691, "Test Method for Determining Axial Pull-Out Strength of Medical Bone Screws". The bone replacement model used for insertion torque, strip-out torque, and pull-out strength was

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

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per Grade 15 of ASTM F1839, "Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments". The test results are summarized below in the risk table. The test report can be found in Appendix C.

There was no significant difference, (b) (4) [redacted] torque, and pull-out strength between the subject and predicate device. The breaking angle for the subject longer length screw (b) (4) [redacted] screws compared to the predicate device.

Potential Risk	Evaluation Method	Acceptance Criteria	Results
Insertion torque higher	Test according to ASTM F1839	(b) (4) [redacted]	
Strip-out torque lower	Testing in Bone model		
Shear-off torque lower	Testing in bone model		
Breaking angle lower	Testing in bone model		
Pull-out Strength lower	Testing according to ASTM F1691		

Chart of Potential Risks for the 8.0 mm Diameter Asnis III Cannulated Screws

6.5 mm diameter Screws

Biomechanical testing was performed comparing the predicate Asnis III Cannulated Screws with the subject modified screw. Shear-off torque, insertion torque and pull-out strength were determined. Pull-out testing was performed per ATSM F1691, "Test Method for Determining Axial Pull-Out Strength of Medical Bone Screws". The bone replacement model used for pull-out strength was per Grade 15 of ASTM F1839, "Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments". Testing determined a significan (b) (4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-9218

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(b) (4) [redacted] The test report can be found in Appendix C.

Potential Risk	Evaluation Method	Acceptance Criteria	Results
Insertion torque higher	Test according to ASTM F1839	(b) (4) [redacted]	
Shear-off torque lower	Testing according to ASTM F1622		
Pull-out Strength lower	Theoretical Calculation		

Chart of Potential Risks for the 6.5 mm Diameter Asnis III Cannulated Screws

Declaration of Conformity

A Declaration of Conformity stating each of the following may be found in Appendix D.

1) A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.
2) A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR §820.30 and the records are available for review.

Clinical Data

Clinical data is not required in support of this 510(k). The design, materials and intended use of the subject components are substantially equivalent to those of predicate components presented under the Substantial Equivalence Information subsection.

Sterility and Packaging Information

The subject device will be packaged in the same manner as the predicate device. Both the subject and predicate Asnis III Cannulated Screw System components are provided both sterile

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

and non-sterile.

Non-Sterile Components:

All parts must be cleaned and sterilized before use, and are recommended to be sterilized by the following procedure:

- Method: Moist heat Sterilization according to ANSI/AAMI/ISO 11134
- Cycle: Saturated Steam with forced air removal
- Temperature: 274°F (134°C)
- Exposure Time: 7 Minutes

The recommended sterilization method has been validated, and yields a Sterility Assurance Level (SAL) of 10^{-6}. The sterility validation method utilized to evaluate the recommended sterilization procedure is in accordance with the AAMI Standards and Recommended Practices, Volume 1: Sterilization. (Other sterilization methods and cycles may also be suitable; however, individuals and hospitals are advised to validate whichever method they deem appropriate at their institution.)

Sterile Components:

The following information details the sterilization method used:

- Radiation Type: Gamma radiation
- Radiation Source: Cobalt 60; gamma
- Sterilization Dose: Minimum dose: 2.5 megarads (25kGy)
- Maximum dose: 4.2 megarads (42kGy)
- Sterility Assurance Level: 10^{-6}
- Sterility Validation Method: The sterilization is validated via the procedure presented in ISO/TR 13409, "Sterilization of Health Care Products Radiation Sterilization Substantiation of 25 kGy as a Sterilization Dose for Small or Infrequent Production Based Batches."

Stryker Trauma AG does not make any claims that the sterile devices are "pyrogen-free."

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

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Packaging Information

All packaging will be of sufficient design and material quality to provide protection from physical damage during transportation and storage.

Non-Sterile Packaging:

Typical packaging used for such applications are medical grade peel packs, blister packs, pouches, boxes with foam compartments, clear plastic tubes with end caps and fiberboard shippers and cartons.

Sterile Packaging:

A double blister package is used to maintain the sterility of the subject devices. Each device is placed in an inner blister pack and sealed, and then placed in a second outer blister pack, and sealed again. This combination is then positioned into a cardboard container with foam inserts, and the cardboard container is sealed via the primary package labels.

Substantial Equivalence Information

Design: The subject modified screws employ the same basic design concepts as the predicate screws. The modification to the predicate stainless steel 8.0 mm diameter Partially Threaded Screws is the addition of longer lengths. The modification of the predicate 6.5 mm diameter Asnis III Cannulated Screws, Partially and Fully Threaded, in both titanium alloy and stainless (b) (4) [redacted] With the exception of the changes described above, the design of the subject device is identical to that of predicate device.

Material: The subject and predicate devices are fabricated from stainless steel and (b) (4) [redacted] (b) (4) [redacted]

Indications: The subject Asnis III Cannulated Screws share the same indication for use as the predicate Asnis III Cannulated Screws. Please refer to the Intended Use subsection at the beginning of Section III of this 510(k) premarket notification, where this information has been provided.

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

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APPENDICES

APPENDIX A **COMPONENT INFORMATION**

APPENDIX B **PACKAGING INFORMATION**

APPENDIX C **MECHANICAL TESTING**

APPENDIX D **STATEMENTS**

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

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APPENDIX A: COMPONENT INFORMATION

A-1 Designation and Description for the Subject Components

A-2 Engineering Drawing for the 8.0 mm diameter Screws

A-3 Engineering Drawing for the 6.5 mm diameter Screws (Stainless Steel)

A-4 Engineering Drawing for the 8.0 mm diameter Screws (b) (4) [redacted]

0034

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Appendix A-1

Designation and Description for the Subject Components

ASNIS III Cannulated Screws ø8.0 mm in Stainless Steel

Device Description	Catalog Number	
	Sterile	Non-Sterile
∅ 8.0 mm Cannulated Screw, length=135 mm, thread length =25mm	326735S	326735
∅ 8.0 mm Cannulated Screw, length=140 mm, thread length =25mm	326740S	326740
∅ 8.0 mm Cannulated Screw, length=145 mm, thread length =25mm	326745S	326745
∅ 8.0 mm Cannulated Screw, length=150 mm, thread length =25mm	326750S	326750
∅ 8.0 mm Cannulated Screw, length=155 mm, thread length =25mm	326755S	326755
∅ 8.0 mm Cannulated Screw, length=160 mm, thread length =25mm	326760S	326760
∅ 8.0 mm Cannulated Screw, length=165 mm, thread length =25mm	326765S	326765
∅ 8.0 mm Cannulated Screw, length=170 mm, thread length =25mm	326770S	326770
∅ 8.0 mm Cannulated Screw, length=175 mm, thread length =25mm	326775S	326775
∅ 8.0 mm Cannulated Screw, length=180 mm, thread length =25mm	326780S	326780

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ASNIS III Cannulated Screws ø6.5 mm in Stainless Steel

Screw Length	Thread Description		
	20mm Thread	40mm Thread	Full Thread
20mm			326420
25mm			326425
30mm			326430
35mm	326035		326435
40mm	326040		326440
45mm	326045		326445
50mm	326050		326450
55mm	326055	326255	326455
60mm	326060	326260	326460
65mm	326065	326265	326465
70mm	326070	326270	326470
75mm	326075	326275	326475
80mm	326080	326280	326480
85mm	326085	326285	326485
90mm	326090	326290	326490
95mm	326095	326295	326495
100mm	326100	326300	326500
105mm	326105	326305	326505
110mm	326110	326310	326510
115mm	326115	326315	326515
120mm	326120	326320	326520
125mm	326125	326325	326525
130mm	326130	326330	326530
135mm	326135	326335	326535
140mm	326140	326340	326540
145mm	326145	326345	326545
150mm	326150	326350	326550

Sterile Screws have a "S" after the catalog number.

0036

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ASNIS III Cannulated Screws ø6.5 mm in Ti-6Al-4V Alloy

Screw Length	Titanium		
	20mm Thread	40mm Thread	Full Thread
20mm			606020
25mm			606025
30mm			606030
35mm	602635		606035
40mm	602640		606040
45mm	602645		606045
50mm	602650		606050
55mm	602655	602855	606055
60mm	602660	602860	606060
65mm	602665	602865	606065
70mm	602670	602870	606070
75mm	602675	602875	606075
80mm	602680	602880	606080
85mm	602685	602885	606085
90mm	602690	602890	606090
95mm	602695	602895	606095
100mm	602700	602900	606100
105mm	602705	602905	606105
110mm	602710	602910	606110
115mm	602715	602915	606115
120mm	602720	602920	606120
125mm	602725	602925	606125
130mm	602730	602930	606130
135mm	602735	602935	606135
140mm	602740	602940	606140
145mm	602745	602945	606145
150mm	602750	602950	606150

Sterile Screws have a "S" after the catalog number.

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

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APPENDIX A-2: ENGINEERING DRAWINGS FOR THE 8.0 MM DIAMETER ASNIS III CANNULATED SCREWS

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0038

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Engineering Diagrams (b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRHFOISTATUS@fda.hhs.gov or 301-796-3113

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APPENDIX A-3: ENGINEERING DRAWINGS FOR THE 6.5 MM DIAMETER ASNIS III CANNULATED SCREWS STAINLESS STEEL

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0040

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

Engineering Diagrams (b) (4)

[redacted]

Engineering Diagrams (b) (4)

[redacted]

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APPENDIX A-4: ENGINEERING DRAWINGS FOR THE 6.5 MM DIAMETER ASNIS III CANNULATED SCREWS Ti-6Al-4V ALLOY

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0043

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

Engineering Diagrams (b) (4)

Engineering Diagrams (3) (4)

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APPENDIX B: PACKAGING INFORMATION

B-1 **Draft Labels for the Subject Components**

B-2 **Package Insert for the Subject Components**

0046

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

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APPENDIX B-1

DRAFT LABELS FOR THE SUBJECT COMPONENTS

0047

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REF 326780 LOT D11111 This Product is NON STERILE CE 0123

Asnis III **ø8.0x180mm TL25mm**

Cannulated Screw

Kanulierte Schraube
Vis canulée
Tornillo canulado
Vite cannulata
Parafuso canulado

Schroef met canule
Kanylerad skruv
Kanuleret skrue
Kanyloitu ruuvi
αυλοφόρος βίδα

QTY 1

2002-09 Swiss Made

stryker Trauma

Stryker Trauma AG
CH-2545 Selzach
A Subsidiary of Stryker Corp. USA

Distributed in USA by
Howmedica Osteonics Corp.
300 Commerce Court
Mahwah, NJ 07430

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

+H82032678019

+$C9400D1111193

Stainless-Steel

V06100

REF 326780S LOT D11111 STERILE R CE 0123

Asnis III **ø8.0x180mm TL25mm**

Cannulated Screw

Kanulierte Schraube
Vis canulée
Tornillo canulado
Vite cannulata
Parafuso canulado

Schroef met canule
Kanylerad skruv
Kanuleret skrue
Kanyloitu ruuvi
αυλοφόρος βίδα

QTY 1

2002-09 Swiss Made

2007-08

stryker Trauma

Stryker Trauma AG
CH-2545 Selzach
A Subsidiary of Stryker Corp. USA

Distributed in USA by
Howmedica Osteonics Corp.
300 Commerce Court
Mahwah, NJ 07430

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

+H820326780S1.

+$C9401D11111.W

Stainless-Steel

V06100

0048

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

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APPENDIX B-2

PACKAGE INSERT FOR THE SUBJECT COMPONENTS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8108

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V15013 / A

stryker Trauma

Manufacturer:
Stryker Trauma AG
Bohnackerweg 1
2545 Selzach
Switzerland
phone: +41 (0) 32 641 66 66
fax: +41 (0) 32 641 66 60

CE 0123

English

Non-Active Implant

Brief Description
Stryker Trauma implants are single use devices intended for the temporary fixation, correction or stabilization of bones. Stryker Trauma implants include varying designs of internal fixation devices and auxiliaries manufactured from materials recognized and accepted for implantation into the body. These materials conform to ASTM and/or ISO standards. For detailed information concerning the identification of the product (such as system association, catalogue no., material, expiration date of sterile products) please refer to the marking on the product and/or the labeling of the package.

Important information
for doctors and OR staff
This package insert does not include all of the information necessary for selection and use of a device. Please see full labelling for all necessary information!
The use of these devices provides the surgeon with a means of bone fixation for the management of fracture and reconstructive surgery. These devices are intended only to assist healing and are not intended to replace normal bone structures. No fracture fixation device that is subject to material fatigue can be expected to withstand activity levels in the same way as would a normal healthy bone. The fracture fixation system, therefore, will not be as strong, reliable or durable as a normal human bone.
Ensure that you are familiar with the intended uses, indications/contraindications, compatibility and correct handling of the implant, which are described in the operative technique manual for the product system. Please remember that product systems may be subject to alterations that affect the compatibility of the implant with other implants or with instruments. For your information, avail yourself of the training courses and publications offered.

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

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Intended Use
The implant is intended for the temporary stabilization of bone segments or fragments until bone consolidation has been achieved.

Indications
The indications for use of these internal fixation devices include:
- bone fracture fixation,
- osteotomy,
- arthrodesis,
- correction of deformity
- revision procedures where other treatments or devices have been unsuccessful,
- bone reconstruction procedures

For detailed information concerning the indications of the implant please refer to the specific operative technique manual of the product system being used.

Contraindications
The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:
- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

WARNINGS AND PRECAUTIONS

WARNING
Implant Selection and Sizing: The correct selection of the fracture fixation appliance is extremely important. Failure to use the appropriate appliance for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the device and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height , weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.
Fixation Screws: Stryker Trauma bone screws are not approved or intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

CAUTION
Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.

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Pre-operative

- The implant is for single use only.
- Implants that came in contact with body fluids should never be reused.
- Ensure that all components needed for the operation are available in the operation theatre.
- Inspection is recommended prior to surgery to determine if instruments or implants have been damaged during storage or prior procedures.

Intra-operative

- Avoid surface damage of implants.
- Discard all damaged or mishandled implants.
- Contouring or bending of an implant should be avoided where possible, because it may reduce its fatigue strength and can cause failure under load. If contouring is necessary, allowed by design or prescribed by Stryker Trauma, the physician should avoid sharp bends, reverse bends or bending the device at a screw hole. Such action must be performed with Stryker Trauma instruments and in accordance with the specified procedures (see operative technique manual). Implants can be available in different versions, varying for example in length, diameter, angle, right-hand and left-hand versions, material and number of drilled holes. Select the required version carefully.
- During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, required for precise positioning and fixing is secure.
- Implants which consist of several components must only be used in the prescribed combination (see operative technique manual).
- After the procedure check the proper positioning of all implants using the image intensifier.
- Do not use components of the StrykerTrauma product systems in conjunction with components from any other manufacturer's system unless otherwise specified (see operative technique manual).

Post-operative

- Post-operative patient activity: These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason post-operative instructions and warnings to patients are extremely important. External immobilization (e.g. bracing or casting) may be employed until X-rays or other procedures confirm adequate bone consolidation.
- The implant is a short-term implant. In the event of a delay in bone consolidation, or if such consolidation does not take place, or if explantation is not carried out, complications may occur, for example fracture or loosening of the implant or instability of the implant system. Regular post-operative examinations (e.g. X-ray checks) are advisable.
- The risk of post-operative complication (e.g. failure of an implant) is higher if patients are obese and/or cannot follow the recommendations of the physician because of any mental or neuromuscular disorder. For this reason those patients must have additional post-operative follow-up.
- Implant removal should be followed by adequate post-operative management to avoid fracture or refracture of the bone.

Informing the patient

The implantation affects the patient's ability to carry loads and her/his mobility and general living circumstances. For this reason, each patient needs individual instructions on correct behavior after the implantation.

The patient should be warned that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma, and that the device has a finite expected service life and may need to be removed at some time in the future.

Explain the need to report unusual changes in the implantation area as well as falls or accidents even if the device or the site of operation did not appear to be harmed at the time.
Explain also the need to appear for the postoperative examinations (e.g. X-ray checks) and for the possible explantation of the implant.

Adverse Effects
In many instances, adverse results may be clinically related rather than device related. The following are the most frequent adverse effects involving the use of internal fracture fixation devices:

- Delayed union or non-union of the fracture site.
- These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. Internal fixation devices are load sharing devices which are intended to hold fractured bone surfaces in apposition to facilitate healing. If healing is delayed or does not occur, the appliance may eventually break due to metal fatigue. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.
- Conditions attributable to non-union, osteoporosis, osteomalicia, diabetes, inhibited revascularization and poor bone formation can cause loosening, bending, cracking, fracture of the device or premature loss of rigid fixation with the bone.
- Improper alignment can cause a mal-union of the bone and/or bending, cracking or even breakage of the device.
- Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
- Early or late infection, both deep or superficial.
- Deep venous thrombosis.
- Avascular necrosis.
- Shortening of the effected bone/fracture site.
- Subclinical nerve damage may possibly occur as a result of the surgical trauma.
- Material sensivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.

Sterilization/Resterilization

DEVICES CONTAINING POLYETHYLENE CANNOT BE RESTERILIZED BY THE USER.

Products delivered sterile have either been exposed to a minimum of 25 kGy of gamma radiation from a cobalt 60 source or have been sterilized by vacuum steam sterilization (please see product label for sterilization method applied). Products not labelled as sterile are non-sterile. The packaging of all sterile products should be inspected for flaws in the sterile barrier or expiration of shelf life before opening. In the presence of such a flaw or expiration of shelf life, the product must be assumed non-sterile. Care must be taken to prevent contamination of the component.

In the event of contamination (unless contaminated with body fluids), or expiration of shelf life or in the case of products supplied non-sterile, the product must be subjected to an appropriate cleaning process and sterilized by means of a validated sterilization procedure before use.
The following process parameters are validated by Stryker Trauma and recommended for resterilization:

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Method: Moist heat sterilization according to ANSI/AAMI/ISO 11134
Cycle: Saturated steam with forced air removal

Exposure phase
Time: 7 minutes
Temperature: 134°C (274°F)

For further information, please refer to the **Instructions for Cleaning and Sterilization of Medical Trauma Devices.**

Explanation of symbols and abbreviations used on product labels

E	sterile, steam
I	sterile, radiation
Δ	date of expiration
A	date of manufacturing
X	see instructions for use
B	single use
♲	international recycling symbol
⊙	green dot, local recycling symbol
QTY	quantity
Φ	batch number
ϑ	catalog number

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

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APPENDIX C: MECHANICAL TESTING

C-1 Test Report Number BML 01/033: Biomechanical Tests on Cannulated Screws – Asnis III ∅8.0 mm

C-2 Test Report Number BML 00/006: Shear Off Torque of ∅6.5 mm cannulated Screws in Stainless Steel

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APPENDIX C-1

TEST REPORT NUMBER (b) (4) [redacted]: BIOMECHANICAL TESTS ON CANNULAED SCREWS – ASNIS III ∅8.0 MM

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stryker Trauma
Selzach AG

(b) (4)

(b) (4)

Title:

Biomechanical Tests on Cannulated Screws
Asnis III ø8.0 mm

(b) (4)

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NB: The test report relates only to the items tested.

NB: Without written approval of the testing laboratory this test report may not be reproduced except in full.

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stryker Trauma Selzach AG

Biomechanics Report (b) (4) [redacted]

(b) (4)

[redacted]

/

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(b) (4) [redacted]

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Results

(b) (4) [redacted]

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(b) (4) [redacted]

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

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Biomechanics Report

(b) (4)

(b) (4)

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(b) (4) [redacted]

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stryker Trauma Selzach AG

Biomechanics Report

(b) (4)

(b) (4)

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Discussion

(b) (4) [redacted]

Insertion Torque

(b) (4) [redacted]

Strip-Out Torque

(b) (4) [redacted]

Shear-Off Torque

(b) (4) [redacted]

Pull-Out Strength

(b) (4) [redacted]

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Conclusion

(b) (4) [redacted]

Reference

(b) (4) [redacted]

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APPENDIX C-2

TEST REPORT NUMBER BML (b)(4) SHEAR OFF TORQUE OF ∅6.5 MM CANNULATED SCREWS IN STAINLESS STEEL

- CONFIDENTIAL -

0068

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

stryker Trauma
Selzach AG

(b) (4)

(b) (4)

Title:

Shear-Off Torque of Ø6.5 mm

(b) (4)

(b) (4)

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

(b) (4)

(b) (4)

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

Introduction

(b) (4) [redacted]

(b) (4) [redacted]

Means and Methods

(b) (4) [redacted]

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

(b) (4)

[redacted]

(b) (4)

[redacted]

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

Results

(b) (4)

[redacted]

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

stryker Trauma Selzach AG

Biomechanics Report

(b) (4)

(b) (4)

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

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(b) (4)

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

stryker Trauma Selzach AG

Biomechanics Repor

(b) (4)

(b) (4)

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

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(b) (4)

[redacted]

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

(b) (4)

(b) (4)

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

(b) (4)

[redacted]

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

Records Processed under FOIA Request # 2015-7975; Released by C

(b) (4)

stryker Trauma Selzach AG

Biomechanics Report

Discussion and Conclusion

(b) (4)

/

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

stryker Trauma Selzach AG

Biomechanics Report (b) (4) [redacted]

ATTACHMENT 1

Testing Protocols and Worksheets (b) (4) [redacted]

Test Number (b) (4) [redacted]

02.02.2000

(b) (6) [redacted]

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

ATTACHMENT 2

Design Drawings for Asnis III prototypes and screw head dimensions

(b) (4) [redacted]

(b) (6) [redacted]

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

APPENDIX D: STATEMENTS

D-1 **Declaration of Conformity**

D-2 **Statement of Scientific Technology and Indications**

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

APPENDIX D-1

Declaration of Conformity

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

DECLARATION OF CONFORMITY

All verification and validation activities were performed by the appropriately designated individual(s), and the results demonstrated that the predetermined acceptance criteria were met.

Howmedica Osteonics' manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR §820.30 and the records are available for review.

William J. Cymbaluk – Vice President
Quality Assurance/ Regulatory Affairs/
Clinical Research

12/6/02
Date

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

APPENDIX D-2

Statement of Scientific Technology and Indications

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

Statement of Scientific Technology and Indications

The indications for use of the subject Asnis III Cannulated Screw System as described in the labeling have not changed from the indications for use of the predicate Asnis III Cannulated Screw System.

In addition, the fundamental scientific technology of the subject Asnis III Cannulated Screw System as described in the labeling has not changed from that of the predicate Asnis III Cannulated Screw System.

William J. Cymbaluk - Vice President
Quality Assurance/Regulatory Affairs/
Clinical Research

12/6/02
Date

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Harry W Demian

Subject: 510(k) Number K024060

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

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

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

This 510(k) contains:

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

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

☐ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

Animal Tissue Source ☐ YES ☒ NO

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

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

Predicate Product Code with class: Class II HWC

Additional Product Code(s) with panel (optional): 888.3030 Single/multi-piece component metallic bone fixation appliances & accessories

Review: Barbara Zimmerman (Branch Chief) OCDB (Branch Code) 12/17/02 (Date)

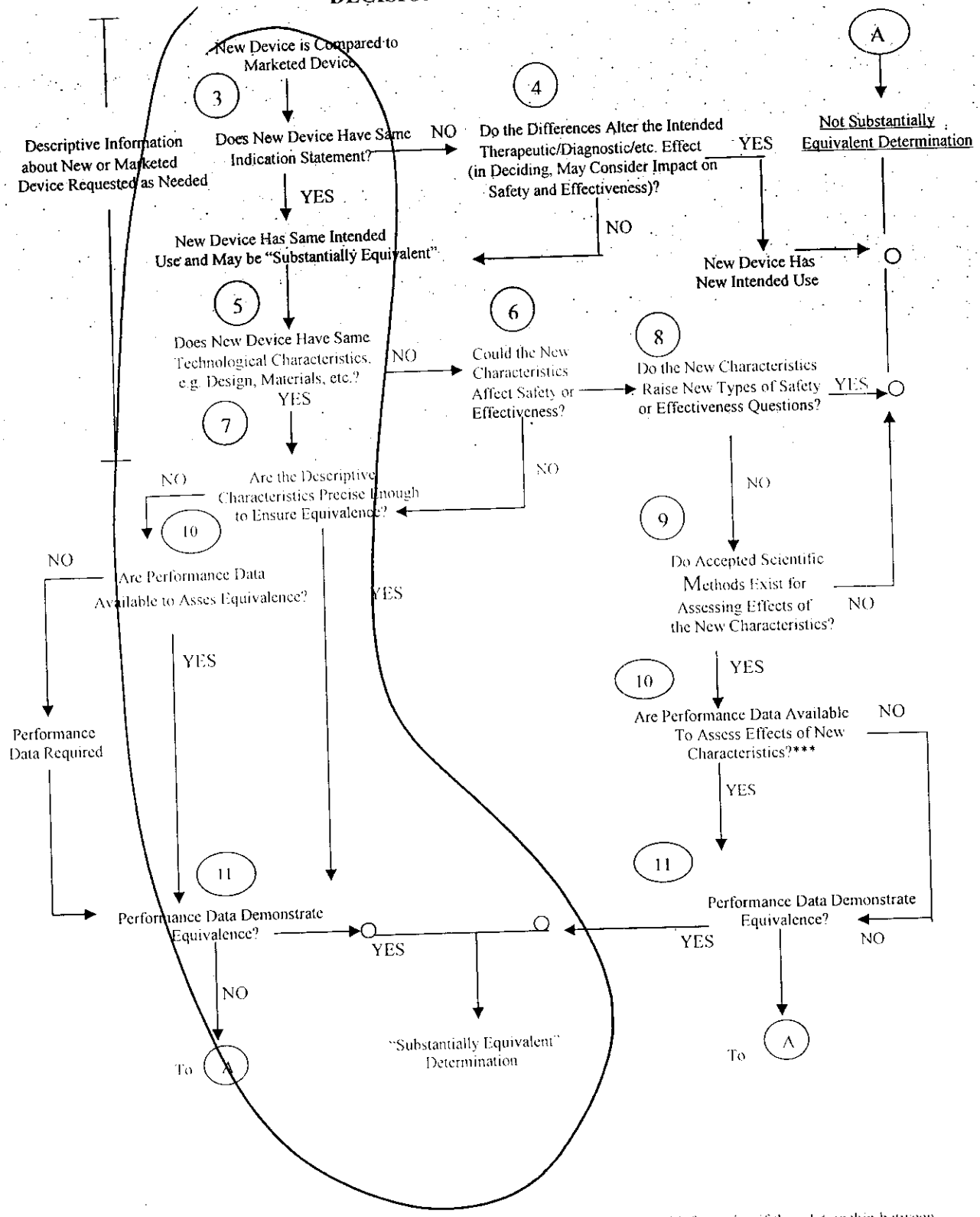
Final Review: Miriam C. Provost for (Division Director) 12/20/02 (Date)

Revised: 8/17/99

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

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



- 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required
- Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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

Records Processed under FOIA Case: 2015-7039, Release Date: 11-30-2015

SPECIAL 510(k) Device Modification

ODE Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K024060

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATIONS,** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

The purpose of this 510K was to address design modifications to the Asnis III cannulated screw system. Additional lengths have been added to the 8.0 mm diameter screws and the core thread diameter of the 6.5 mm diameter screws have been increased.

Device Description: The modifications to the predicate stainless steel 8.0 diameter partially threaded screws is the addition of longer lengths. Lengths range from 135-180 mm in 5mm increments will be added to the system. With the exception of the additional length, the design of the subject device is identical to that of the predicate device.

The modifications of the predicate 6.5mm diameter Asnis III cannulated screws, partially and fully threaded, in both titanium and stainless steel, is the increase in core thread diameter from 4.5mm to 4.75mm.

The sponsor looked at inertion torque force, strip-out torque, shear-off torque, breaking angle, and pull out strength. All results were considered acceptable.

4. **Design Control Activities Summary** which includes:

   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 verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied was provided.
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

5. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

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

 Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

(Reviewer's Signature) (Date)

Comments

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

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

510(k) Number: K024060

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. *		
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.

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

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

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

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

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

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

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

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

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

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

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

Passed Screening X Yes ____ No
Reviewer: [signature]
Concurrence by Review Branch: _____

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

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

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 024060

Reviewer: Harry W Demian

Division/Branch: DGRND/ORDB

Device Name: ASNIS III

Product To Which Compared (510(K) Number If Known): K000080

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

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

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

1. Intended Use:

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

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

1. Explain why not a device:

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

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

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

5. Describe the new technological characteristics:

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

7. Explain how descriptive characteristics are not precise enough:

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

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

10. Explain what performance data is needed:

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

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

Records Processed under FOIA Request # 2015-7975; Released by CDRH on 11-30-2015

Internal Administrative Form

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

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