K133285

APR 09 2014

stryker

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510(k) Summary of Safety and Effectiveness:

Stryker Temporary Condylar Prosthesis

Sponsor:	Stryker Leibinger GmbH & Co. KG Boetzinger Strasse 41 79111 Freiburg, Germany
Proprietary Name:	Stryker Temporary Condylar Prosthesis
Common Name:	Temporary mandibular condyle reconstruction plate
Classification Name and Reference:	21 CFR §872.4770 - Temporary mandibular condyle reconstruction plate
Regulatory Class:	Class II
Device Product Code(s):	NEI
Predicate devices:	**K020199** - Locking Reconstruction Plate with Attachable Condylar Head
510(k) Contact Person:	Jamshed Badarpura Stryker Craniomaxillofacial 750 Trade Centre Way, Suite 200 Portage, MI 49002 Phone: 269-389-4260 Fax: 877-648-7114 jamshed.badarpura@stryker.com
Date Prepared:	October 24, 2013

Introduction:

A Traditional 510(k) is being submitted to the FDA to grant clearance to market the Stryker Temporary Condylar Prosthesis cleared via K020199 with the proposed modification.

Proposed Modification:

Change in material composition of coating used on the head of Stryker Temporary Condylar Prosthesis.

Intended Use:

Stryker Temporary Condylar Prostheses are intended for temporary (not exceeding 24 months) reconstruction in patients undergoing ablative tumor surgery requiring removal of the mandibular condyle.

Device Description:

The Stryker Temporary Condylar Prosthesis is an independent solid condylar head which is rigidly connected to a standard or locking Stryker Reconstruction plate via fastening screws. The Temporary Condylar Prosthesis is provided in a left and right configuration and is intended for temporary use only (not exceeding 24 months). The Condylar Prosthesis is made of commercially pure titanium and the head of the condyles is PVD (Physical Vapor Deposition) coated which differentiates it from the rest of the condyles giving it golden color. The Temporary Condylar Prosthesis is accompanied by connecting screws which are made of commercially pure titanium alloy and are specifically designed to fixate the Prosthesis with a Stryker plate.

Technological Characteristics:

The subject Stryker Temporary Condylar Prosthesis when provided with the new coating material will have very similar technological characteristics as its originally cleared predicate version. The Temporary Condylar Prosthesis will have the exact same design and dimensions, and will be fabricated from commercially pure titanium. The connecting screws will also remain unchanged with respect to design and material composition. The

only difference in the subject condyles from its earlier version will be difference in material composition of the coating material on head of the condyles.

Summary of Performance Testing:

The Stryker Temporary Condylar Prosthesis was subject to Verification and Validation testing to ensure that the new coating is safe and effective, and the design outputs of the modified device meets the design inputs of the originally cleared device. Various tests like friction behavior, roughness, thickness, wear resistance, adhesion strength and hardness were conducted to verify mechanical wear and integrity of the new coating material. Additionally, biocompatibility and corrosion tests were performed to ensure that the new coating material is biocompatible and corrosion resistant.

Substantial Equivalence:

The Stryker Temporary Condylar Prosthesis is substantially equivalent to its originally cleared version (predicate) with regards to Intended Use, design, principle material composition and operational principle. Further, results from performance testing confirm that the difference in material composition of coating material does not affect the safety and effectiveness of the device.

Predicate Device -

Locking Reconstruction Plate with Attachable Condylar Head - K020199

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

April 9, 2014

Stryker Leibinger GmbH & CO. KG
C/O Mr. Jamshed Badarpura
Stryker Craniomaxillofacial
750 Trade Centre Way
Suite 200
Portage, MI 49002 US

Re: K133285
Trade/Device Name: Stryker Temporary Condylar Prosthesis
Regulation Number: 21 CFR 872.4770
Regulation Name: Temporary Mandibular Condyle Reconstruction Plate
Regulatory Class: Class II
Product Code: NEI
Dated: March 20, 2014
Received: March 20, 2014

Dear Mr. Badarpura:

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133285

Stryker Temporary Condylar Prosthesis

Indications for Use:

Stryker Temporary Condylar Prostheses are intended for temporary (not exceeding 24 months) reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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