K121235

JAN - 9 2014

510(k) Summary of Safety and Effectiveness

Proprietary Name:	The Leibinger Advance Internal Midface Distraction System
Common Name:	Bone Distraction System
Classification Name and Reference:	Smooth or Threaded metallic bone fixation fastener 21 CFR § 888.3040
Proposed Regulatory Class:	Class II
Product Codes:	JEY – Bone Plate
Submitter:	Stryker Craniomaxillofacial 750, Trade Centre Way Portage MI 49002 Phone: (269) 389-4260
Contact:	Jamshed Badarpura Regulatory Compliance Analyst Phone: (269) 389-4260 Jamshed.badarpura@stryker.com
Date Prepared:	April 23, 2012
Predicate Devices:	Cohen Distractor (K972154), Synthes Midface Distractor (K022005), Molina Orbital Malar Distractor (K003883), Leibinger Advance Internal Midface Distraction System (K092743).

Description:

The Leibinger Advance Internal Midface Distraction System is a distraction system consisting of the following major components: a distractor frame which incorporates connection screws for the plates, a removable activation rod, plates, and an activation key. The plates and frame initially stabilize and then gradually distract the osteotomy. The removable activation rod, covered with a protective sheath, is connected to the frame and provides the point of attachment for the activation key used to initiate the distraction of the osteotomy.

Intended Use:

The Leibinger Advance Internal Midface Distraction System is intended to be used for cranial, monobloc and/or midface distraction osteogenesis of the craniofacial skeleton.

Indications:

The Leibinger Advance Internal Midface Distraction System is indicated for the treatment of syndromic and non-syndromic craniosynostosis, midface retrusion, congenital midfacial hypoplasia, and craniofacial dysostosis in patients two years of age and older.

Technological Characteristics:

The Leibinger Advance Internal Midface Distraction System is similar to its predicate devices in the following technological characteristics:

1. **Operational Principle:**

   The basic operational principle for the predicate devices, as well as the subject device is the same for midface and cranial distraction. The method of site preparation and insertion are similar for all of the devices.

2. **Material Information:**

   The distractor is made of stainless steel and titanium alloy. The activation rod is made of stainless steel and has an outer sheath of Polytetrafluoro-ethylene (PTFE). Plates and screws are made of either pure titanium or titanium alloy. All materials in the system are biocompatible, corrosion-resistant and non-toxic in the biological environment.

3. **Design:**

   The Leibinger Advance Internal Midface Distraction System has operational design principles identical to the predicate Cohen Distractor System determined substantially equivalent via 510(k) K972154. Both use an external activation key to interface with a percutaneous activation rod to initiate distraction of the distractor frame unit. The plates are nearly identical in design with only the configuration of screw holes and sizes differing.

4. **Packaging:**

   The devices of the Leibinger Advance Internal Midface Distraction System will be delivered non-sterile, same as the predicate.

Clinical:

No clinical testing was performed to support this submission.

Non-Clinical Testing:

The Leibinger Advance Internal Midface Distraction System successfully passed all tests conducted with regards to biocompatibility, cleaning, sterilization, corrosion resistance, determination of moments of inertia of plates, four point bending of distractor with plates, in-plane and out-of-plane bending tests.

Substantial Equivalence Discussion:

The Leibinger Advance Internal Midface Distraction System is substantially equivalent to below listed legally marketed predicate devices in regards to intended use, design, materials, and operational principles. It is also as safe and as effective for the proposed indications as the predicate devices.

- Howmedica Osteonics Cohen Distractor: K972154
- Synthes Midface Distractor: K022005
- Molina Orbital Malar Distractor: K003883
- Leibinger Advance Internal Midface Distraction System (K092743)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 9, 2014

Stryker Craniomaxillofacial
Mr. Jamshed Badarpura
Regulatory Compliance Analyst
750, Trade Centre Way
Portage, MI 49002

Re: K121235
Trade/Device Name: The Leibinger Advance Internal Midface Distraction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: II
Product Code: JEY
Dated: January 3, 2014
Received: January 6, 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" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Mary S. Runner -S

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 Statement

510(k) Number (if known): K121235

Device Name: The Leibinger Advance Internal Midface Distraction System

Indications for Use:

The Leibinger Advance Internal Midface Distraction System is indicated for the treatment of syndromic and non-syndromic craniosynostosis, midface retrusion, congenital midfacial hypoplasia, and craniofacial dysostosis in patients two years of age and older.

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)

Susan Runner DDS, MA Mary S. Runner -S 2014.01.09 09:32:37 -05'00'