OCT 27 2005

K051871

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS IN ACCORDANCE WITH SMDA OF 1990

DATE: 2005-08-22

APPLICANT: Storz am Mark GmbH
Emminger Str. 39
D-78576 Emmingen-Liptingen
Germany
Phone: +49 (7465) 9260-0
Fax: +49 (7465) 9260-50
Email: info@stoma.de

Official Correspondent: Gunther Schanz

1. Device Name

Trade Name: STOMA Bone Screw
Common Name: Bone Screw

2. Classification

The products are classified according following Device Names and Product Codes:

Device:	Screw, Fixation, Intraosseous
Medical Specialty:	Dental
Product Code:	DZL
Regulation Number:	872.4880
Device Class:	2
Description acc. 21 CFR 872.4880: Subpart E -- Surgical Devices Sec. 872.4880 Intraosseous fixation screw or wire. (a) *Identification.* An intraosseous fixation screw or wire is a metal device intended to be inserted into fractured jaw bone segments to prevent their movement. (b) *Classification.* Class II.	

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3. Description of the Device

3.1. Indication for Use

STOMA Bone Screws are developed and manufactured to be used as non-active bone surgery implants for the treatment of bone fractures, especially for the fixation of transplanted bone blocks during the augmentation process and / or in combination with bone plates and bone meshes in the oral cavity and maxillomandibular surgical field.

3.2. Properties

The bolt head of the STOMA Bone Screw is either self tapped by a square, hexagon or cross slot. The screws will be delivered in a cassette / container including accordingly screw driver and pilot drill. The bone screws are available in 1.3mm in length 4 mm to 10mm and 1.6mm and 2.0mm diameter and lengths ranging from 4mm to 16mm.

4. Substantial Equivalence Comparison

STOMA Bone Screws are substantially equivalent to other legally marketed bone screws from different manufacturers, e.g. OSTEOMED CORP. (K961418), KLS-Martin MMF Screw (K980760) and/or Synthes (USA) 1.3 Craniofacial Srews (K021850).

5. Biocompatibility

All requirements of biocompatibility are meet through the composition of the used material. The used titanium alloy is also used in many other medical devices, especially implants.

Compared with competitors devices, STOMA Bone Screws are made out of substantially equivalent or identical material.

6. Sterilization by User

STOMA Bone Screws are delivered in non-sterile conditions. The user may sterilize these devices by using a validated steam-sterilization process according DIN EN 554 / ISO 11134 that uses a sterilization cycle of 137°C / 280°F, 3 bar, for min. 15 minutes.

7. Conclusion

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that STOMA Bone Screws are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2005

Storz am Mark GmbH
C/O Mr. Franz Menean
Managing Director
Medagent GMBH & Co. KG
Griesweg 47
Muehlheim
GERMANY 78570

Re: K051871
Trade/Device Name: STOMA BONE SCREW
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous fixation screw or wire
Regulatory Class: II
Product Code: DZL
Dated: August 22, 2005
Received: August 30, 2005

Dear Mr. Menean:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number: K 051871

Device Name: **STOMA Bone Screw**

Indications for Use:

STOMA Bone Screws are developed and manufactured to be used as non-active bone surgery implants for the treatment of bone fractures, especially for the fixation of transplanted bone blocks during the augmentation process and / or in combination with bone plates and bone meshes in the oral cavity and maxillomandibular surgical field.

Prescription Use __YES___ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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