K09 1390

JUL 30 2009

510(k) Summary for the

Sterile Self Ligating Spider Screw

This Special 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

General Information

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Summary Preparation Date: April 30, 2009

Names

Device Name:	Sterile Self Ligating Spider Screw
Classification Name:	Endosseous dental implant
Product Code:	OAT
Regulation Number:	872.3640
Device Class:	Class II

Device Description

The Sterile Self Ligating Spider Screw is a titanium fixation device to be inserted into the upper or lower jaws, designed to be immediately used (after the bone insertion) as fixation for orthodontic appliances. It is used temporarily and must be removed after the orthodontic treatment has been completed. It is provided sterile and is intended for single use only. The Sterile Self Ligating Spider Screw is provided in "Self Drilling and Self Tapping" configuration and is manufactured from Grade 5 Titanium alloy according to ASTM F136-98 standard. Sterile Self Ligating Spider Screw is provided with different diameters, lengths and head shapes.

Predicate Devices

The Sterile Self Ligating Spider Screw is substantially equivalent to the following predicate device, which is legally marketed in the United States:

Applicant	*Device name*	*510(k) Number*
HDC S.r.l.	HDC Sterile Spider Screw	K071851

The components of Sterile Self Ligating Spider Screw have been compared in terms of intended use, design characteristics, and safety solutions with the predicate device. Complete substantial equivalence information is provided in the Section XI of this submission.

Intended Use

The Sterile Self Ligating Spider Screw is a threaded titanium dental implant screw, intended to serve as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily and must be removed after the orthodontic treatment has been completed. It is provided sterile and is intended for single use only.
The Indications for use are substantially unchanged compared with K071851. The only changes are relevant to the fixation instructions of the Sterile Self Ligating Spider Screw: these instructions are added to the predicate's one.

Fundamental Scientific Technology

The Sterile Self Ligating Spider Screw does not introduce changes compared with the predicate device with regards to the Fundamental Scientific Technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

HDC S.r.l.
C/O Mr. Guido Bonapace
Regulatory Consultant
ISEMED S.r.l.
Via Borgo Santa Cristina, 12
40026 Imola (BO)
ITALY

Re: K091390
Trade/Device Name: Sterile Self Ligating Spider Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: June 30, 2009
Received: July 2, 2009

Dear Mr. Bonapace:

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

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

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

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

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

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division 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 STATEMENT

Special 510(k) Number (if known): K091390

Device Name: Sterile Self Ligating Spider Screw

Indications for Use:

The Sterile Self Ligating Spider Screw is a threaded titanium dental implant screw, intended to serve as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. The device is used temporarily and shall be removed after orthodontic treatment has been completed. It is provided sterile and is intended for single use only.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K091390