K122069

APR 1 1 2013

510(k) Summary

Submitter's name: Address:	Lancer Orthodontics 2330 Cousteau Court Vista, California 92081 Telephone: 1-800-854-2896 Facsimile: (760) 744-5724
Name of contact person:	Larry Walker Regulatory & Quality Systems Manager Lancer Orthodontics 2330 Cousteau Court Vista, California 92081 Telephone: (760)-304-2746 Facsimile: (760) 744-5724 Email: gserrano@lancerortho.com
Date the summary was prepared:	April 4, 2013
Name of the device:	Mini screw
Trade or proprietary name:	Storm Mini Screw
Common or usual name:	Orthodontic mini screw
Regulation description	Endosseous dental implant
Class	II (two)
Product Code:	OAT
21 CFR Regulation Number:	872.3640

The legally marketed device to which we are claiming equivalence as per CFR 21 872.3640:

HDC Spider Screw – Temporary Anchorage Device System, 510(k) reference number K071851

T.O.A.D.S., LLC, Orthodontic TAADS (Temporary Anatomical Anchor Device System), 501(k) reference number K063149

Description of the device:

The Storm Mini screw is a self-tapping and self-drilling screw constructed of grade 5 titanium (Ti6Al4V) and anodized for the ease of identification through color. After bone insertion, the Storm Mini Screw is designed

to be immediately used as an anchorage for orthodontic devices.

The Storm mini-screw head is designed to facilitate placement of orthodontic appliances such as wires, springs, and elastic ligatures. The Storm Mini Screw is intended for single use only and used temporarily and must be removed after orthodontic treatment has been completed.

Intended Use:

The Storm Mini Screw is a threaded titanium dental implant screw intended to provide a fixed anchorage point for the attachment of orthodontic appliances and facilitate the orthodontic movement of teeth. It is used temporarily and must be removed after orthodontic treatment has been completed. The Storm Mini Screw is provided sterile and is intended for single use only.

Description of Performance Tests:

The Storm Mini Screw has been tested to verify performance characteristics under a static load resistance in order to simulate the geometric conditions to which the device would be subjected to in clinical practice. Static load tests were performed by applying a load at 90° with respect to the axis of the Storm Mini Screw. The test results concluded that the Storm Micro Screw provides adequate mechanical strength for its intended use in an orthodontic application and has equivalent performance to the predicate devices. Tests for sterilization validation indicated that treatment method reached the established VD Max[25] dosage. Test certifications performed after sterilization and accelerated ageing confirmed a 5 year sterile shelf life.

Summary of Substantial Equivalence:

Lancer Orthodontics has identified two predicate devices: the Sterile Spider Screw from HDC s.r.l. (ref. K071851) and Orthodontics TAADS from T.O.A.D.S LLC (ref. K063149). The Storm Mini Screw was compared to the two predicate devices in the following areas and was found to have similar or better technological characteristics and was determined to be substantially equivalent:

	Storm Mini Screw	**Predicate, HDC Spider Screw**	**Predicate, Orthodontic TAADS**
Intended Use	The Storm Mini Screw is a threaded titanium dental	The HDC sterile Spider Screw is a threaded titanium	The Orthodontic TAADS Screws are intended to

	implant screw intended to provide a fixed anchorage point for the attachment of orthodontic appliances and facilitate the orthodontic movement of teeth. It is used temporarily and must be removed after orthodontic treatment has been completed. The Storm Mini Screw is provided sterile and is intended for single use only.	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.	provide a fixed anchorage point for the attachment of orthodontic appliance to facilitate the orthodontic movement of teeth. They are intended for temporary use and should be removed after orthodontic treatment has been completed. The screws are intended for single use only.
Target Population	People having orthodontia work	People having orthodontia work	People having orthodontia work
Technological Characteristics	Self-drilling and Self-tapping Orthodontic head for appliance placement Two different diameter bodies: 1.5 mm and 2.0 mm Conical thread with asymmetrical profile Single use Length 8 mm & 10 mm The neck length of transmucosal portion is variable to provide adaptation for different intraoral mucosa thickness: neck lengths: 1.5 and 3 mm	Self-drilling and Self-tapping Orthodontic head for appliance placement Two different diameter bodies: 1.5 mm and 1.9 mm Conical thread with asymmetrical profile Single use Length range: 5 mm - 11 mm The neck length of transmucosal portion is variable to provide adaptation for different intraoral mucosa thickness: neck length 1 and 2 mm	Not self-drilling (requires pre-drilling), Self-tapping Orthodontic head for appliance placement Two different diameter bodies: 1.5 mm and 2.5 mm Conical thread with asymmetrical profile Single use Length (information not publicly available) Neck Length (information not publicly available)
Materials	Grade 5 Titanium ASTM F136-95 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications	Grade 5 Titanium ASTM F136-95 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications	Grade 5 Titanium ASTM F136-95 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
	Storm Mini Screw	**Predicate, HDC Spider Screw**	**Predicate, Orthodontic TAADS**
Where Used	Dental and orthodontic specialists offices	Dental and orthodontic specialists offices	Dental and orthodontic specialists offices

Sterility	Sterile via beta irradiation 5 year Sterile Shelf Life	Sterile via gamma radiation Shelf Life of Sterility is not publicly available information	Sterile and non-sterile, (Information on method of sterilization is not publicly available) Shelf Life of Sterility is not publicly available information
Biocompatibility	Made of biocompatible, medical grade anodized titanium ISO 10993 compliant	Made of biocompatible, medical grade titanium	Made of biocompatible, medical grade anodized titanium
Anatomical Sites	Maxillary edentulous alveolar ridges Maxillary Buccal/lingual interradicular areas Mandibular edentulous alveolar ridges Mandibular Buccal/lingual interradicular areas Mandibular Buccal shelf at the oblique area Mandibular retromolar area	Maxillary edentulous alveolar ridges Maxillary Buccal/lingual interradicular areas Mandibular edentulous alveolar ridges Mandibular Buccal/lingual interradicular areas Mandibular Buccal shelf at the oblique area Mandibular retromolar area	Unknown from published documentation
Mechanical Safety	ASTM F136-95 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications	ASTM F136-95 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications	ASTM F136-95 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications

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

April 11, 2013

Mr. Larry Walker
Regulatory & Quality Systems Manager
Lancer Orthodontics
2330 Cousteau Court
VISTA CA 92081

Re: K122069
Trade/Device Name: Storm Mini Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: March 8, 2013
Received: March 11, 2013

Dear Mr. Walker:

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,

Kwame O. Ulmer-S for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K122069

Device Name: Storm Mini Screw

Indications For Use:

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner, DDS, MA Mary S. Runner -S 2013.04.09 13:32:42 -04'00'

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

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