K082800

510(k) Summary

1. Applicant's Name and Address

Park Dental Research Corp.
19 West 34th Street (Suite 301)
New York NY 10001

AUG 2 6 2010

Submitted by:

Daniel J. Manelli
Manelli & Fisher, P.L.L.C.
5335 Wisconsin Avenue NW (Suite 440)
Washington, DC 20016
Telephone: 202-885-5548

2. Name of the Device:

Trade Name: Star/Vent Internal Hex Screw Implant
Common Name: Endosseous dental implant
Classification Name: Endosseous dental implant

3. Substantial Equivalence:

Alpha Bio (K063364)
3i Osseotite (K022009, K022113
Mis (K04007, K003191)

4. Description of the Device

The Park Star/Vent Internal Hex Screw Implant is a root form endosseous dental implant (FDA classification code DZE). It has been placed in class 2 per 21 CFR 872.3640. The device is fabricated from titanium alloy meeting the specifications of ASTM F136. It is available in lengths of 8, 10, 11.5, 13, and 16mm and diameters of 3.3, 3.75, 4.2, 5.0 and 6.0mm. The surface is treated with resorbable blast media. The device is provided sterile. Sterility is achieved by gamma radiation pursuant to ISO 11137 to provide a sterility assurance level (SAL) of 10^{-6}. This device includes straight abutments with a 1, 2, 3, or 4mm collar and a straight UCLA cast abutment with a titanium base. These abutments are composed of titanium alloy meeting the specifications of ASTM F-136.

5. Intended use of the device

The Star/Vent Internal Hex Screw Implant is intended for placement in the bone of the upper or lower jaw to support prosthetic devices such as artificial teeth, crowns, bridges or overdentures in edentulous or partially edentulous patients and to restore the patient's chewing function. It is intended for immediate loading when good primary stability has been achieved and with appropriate occlusal loading,

6. Basis for Substantial Equivalence

The Star/Vent Internal Hex Screw Implant is substantially equivalent to the above identified implants from the standpoint of material composition, implant dimensions (e.g., AlphaBio K063364: lengths 8, 10, 11.5, 13. 16mm; diameters 3.3, 3.7, 4.2, 5.0mm), surface treatment and indications for use. It incorporates no novel technological characteristics, unique indications or materials as compared with the predicate devices.

(revised 8/23/10)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Park Dental Research Corporation
C/O Mr. Daniel J. Manelli
Manelli & Fisher, P.L.L.C.
5335 Wisconsin Avenue NW, Suite 440
Washington, DC 20015

AUG 2 6 2010

Re: K082800
Trade/Device Name: Star/Vent Internal Hex Screw Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: August 23, 2010
Received: August 24, 2010

Dear Mr. Manelli:

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 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/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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082800

Indications for Use

510(k) Number: K082800

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Prescription Use __X__
(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____
(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

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