K 100182

SALVIN®
Dental Specialties

MAY 10 2010

Salvin Dental Specialties, Inc
3450 Latrobe Drive • Charlotte, NC 28211 • Phone 704-442-5400 • Fax 704-442-5424

510(k) Summary

A	510(k) Owner	Salvin Dental Specialties, Inc 3450 Latrobe Drive Charlotte, NC 28211
	Contact	Robert Salvin CEO Salvin Dental Specialties, Inc. 3450 Latrobe Drive Charlotte, NC 28211 (704) 442-5400 (704) 442-5424 bobsalvin@salvin.com
	Preparation Date	December 22, 2009
B	Trade Name	Salvin Dental Specialties, Inc. Bone Tack System
	Common Name	Membrane Fixation System
	Classification Name	Screw, Fixation, Intraosseous (21 CFR 872.4880, Product code DZL)
C	Predicate Device(s)	K973180 – IMTEC Bone Tac
D	Device Description	The *Salvin Bone Tack System* consists of 3mm and 5mm Titanium (Ti-6Al-4V) bone tacks and associated instrumentation. The devices are provided non-sterile.
E	Intended Use	The Salvin Bone Tack System is designed to stabilize a barrier membrane onto a region of cortical plate. This may be used in craniofacial, maxillofacial, or mandibular bone. Considerations such as quality of bone, bone type, functional loads exerted, general patient health and others should be carefully evaluated prior to use.

F	Technological Characteristics	As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States. Engineering drawings, labeling, and detailed inspectional analysis have demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device.
G	Non-Clinical Testing	Analysis based on engineering review and inspection of actual parts
H	Clinical Testing	Not applicable to this device
I	Conclusions	Based on the 510(k) Summary and the information provided herein, we conclude that the *Salvin Bone Tack System* is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.

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

MAY 10 2010

Mr. Robert Salvin
Chief Executive Office
Salvin Dental Specialties, Incorporated
3450 Latrobe Drive
Charlotte, North Carolina 28211

Re: K100182
Trade/Device Name: Salvin Dental Specialties Fixation Screw
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: April 2, 2010
Received: April 30, 2010

Dear Mr. Salvin:

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

Indications for Use

510(k) Number (if known): K100182

Device Name: Salvin Dental Specialties Fixation Screw

Indications for Use:

The Salvin Bone Tack System is designed to stabilize a barrier membrane onto a region of cortical plate. This may be used in craniofacial, maxillofacial, or mandibular bone. Considerations such as quality of bone, bone type, functional loads exerted, general patient health and others should be carefully evaluated prior to use.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for M.S.R.

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

510(k) Number: K100182