DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 28, 2017

Salvin Dental Specialties
% John Kapitan
CEO
Kapstone Medical, LLC
Po Box 969
Leicester, North Carolina 28748

Re: K161857
Trade/Device Name: Salvin Tenting Screw System
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: March 30, 2017
Received: March 31, 2017

Dear John Kapitan:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

7. Indications for Use Statement

510(k) Number (if known): _____

Device Name: Salvin Tenting Screw System

Indications for Use:

The Salvin Tenting Screw System is used to stabilize, fixate, and/or support bone grafts, bone filling materials and /or barrier membranes used for regeneration of bone in the oral cavity.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

1. Applicant

Salvin Dental Specialties, Inc.
3450 Latrobe Drive
Charlotte, NC 28211

2. Official Correspondent

Kapstone Medical LLC PO
Box 969
Leicester, NC 28748

Contact Person:
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Email: jkapitan@kapstonemedical.com

3. Date Prepared:

March 30, 2017

4. Device Name

Common/Usual Name:	Tenting Screw System
Classification Name:	Intraosseous Fixation Screw or Wire
Regulation Number:	21CFR 872.4880
Product Code:	DZL
Classification:	II
Panel:	Dental

5. Predicate Devices

The Salvin Tenting Screw System is substantially equivalent to the Pro-Fix™ Tenting Screw produced by Osteogenics Biomedical. The Pro-Fix™ Tenting Screw is the Primary Predicate and the Salvin Fixation Screw System is a Reference Predicate.

Predicate	510(k) Number	Device	Manufacturer
Primary	K093719	Pro-Fix™ Tenting Screw	Osteogenics Biomedical
Reference	K073342	Salvin Dental Fixation Screw System	Salvin Dental Specialties

6. Description of the Device

The Salvin Tenting Screw System is a set of bone screws and instrumentation. The system consists of a set of screws (one diameter and three lengths) and the driver used to implant these screws. The devices are delivered non-sterile. The screws are made from titanium alloy (Ti-6Al-4V ELI), as described by ASTM F136.

The screws come in one diameter – 1.5mm (5.0mm head diameter), and three lengths – 7mm, 8mm, and 9mm. The screws incorporate a 4mm thread length adjacent to a polished neck.

7. Indications for Use

The Salvin Tenting Screw System is used to stabilize, fixate, and/or support bone grafts, bone filling materials and /or barrier membranes used for regeneration of bone in the oral cavity.

8. Summary of Technological Similarities and Differences

The Salvin Tenting Screw is substantially equivalent to the primary predicate – the Osteogenics Pro-Fix™ Tenting Screw in terms of material, geometry, and mechanical performance. The Salvin Fixation Screw is a reference predicate with technological similarities in terms of material, geometry, and manufacturing processing.

Applicant	**Salvin Dental**	**Osteogenics**	**Salvin Dental**
	SUBJECT DEVICE	**PRIMARY PREDICATE**	**REFERENCE PREDICATE**
Product Name	**Tenting Screw**	**Pro-Fix™**	**Fixation Screw**
510(k) Number	K161857	K093719	K073342
Product Code	DZL	DZL	HWC
Regulation #	21CFR 872.4880	21CFR 872.4880	21CFR 888.3040
Class	II	II	II
Prescription or O-T-C?	Prescription	Prescription	Prescription
Provided Sterile or Non-sterile?	Non-sterile	Non-sterile	Non-sterile
Indications for Use	The Salvin Tenting Screw is used to stabilize, fixate, and/or support bone grafts, bone filling materials and /or barrier membranes used for regeneration of bone in the oral cavity.	The Pro-Fix™ Precision Fixation System is used to stabilize, fixate, and/or support bone grafts, bone filling materials and /or barrier membranes used for regeneration of bone in the oral cavity.	The Salvin Fixation Screw is intended for use in internal fixation of small bones including the craniofacial and maxillofacial skeleton affected by trauma, or for reconstruction.
Components and Size(s)	Diameter: 1.5mm Lengths: 7, 8, and 9mm	Diameter: 1.5mm Lengths: 7, 8, and 9mm	Diameters: 1.5 and 2.0mm Lengths: 4, 6, 8, 10, 13, 15, 17mm

Applicant	Salvin Dental	Osteogenics	Salvin Dental
	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE
Product Name	Tenting Screw	Pro-Fix™	Fixation Screw
Device/Implant Materials	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V ELI per ASTM F136
Manufacturing & Cleaning	Proprietary Process Shared with Salvin Fixation Screw	Unknown	Proprietary Process Shared with Salvin Tenting Screw
Sterilization Methodology	Steam	Steam	Steam

9. Summary of Performance Data

Specific Tests Performed:

- ASTM F543-13
  - Torsional Properties
  - Drive Torque
  - Axial Pullout
  - Self-Tapping Force
- Sterilization Validation

Bench testing including axial pullout and torque to failure, as well as geometric comparisons of the Salvin Tenting Screw device to the Osteogenics Pro-Fix™ device demonstrated substantial equivalence. The results for Sterile Validation met the acceptance criteria.

10. Conclusion

The Salvin Tenting Screw is substantially equivalent to the Osteogenics Pro-Fix™ predicate device (Primary Predicate - K093719). In addition to conclusions from performance testing and geometric comparisons, the devices have the same "Indications for Use," are available by prescription only, utilize Ti-6Al-4V ELI material, and are provided non-sterile for single-use only. It can be concluded that the Salvin Tenting Screw is substantially equivalent to the predicate device.