JUL 0 8 2014

Section 5: 510(k) Summary K140144

centrix
Making Dentistry Easier.℠

Submitter:

Centrix, Inc.
770 River Road
Shelton, CT 06484
203-567-7444 – Telephone
203-567-7444 – Facsimile
Greg Moreau – Contact Person

Date Summary Prepared: January 17, 2014

- Trade Name – Benda Wedge
- Common Name – Dental Wedge
- Classification Name – Dental Hand Instrument, Class 1 (21 CFR Sec. 872.4565, EJB)

Devices for Which Substantial Equivalence is Claimed:

- Wedge Wands, G-Wedges, Class 1 Medical Devices, Product Code EJB, Garrison
- Pascord, Siltrax, Pre-Amendment Class U Medical Devices, Product Code MVL, Pascal

Summary

Device Description

Benda Wedge is indicated for use as a temporary inter-proximal wedge during dental restorative procedures. Benda Wedge is similar in design to the Wedge Wand predicate device but includes a hemostatic agent to control gingival bleeding.

Design features consist of the following:

- Available in four anatomically-shaped sizes for optimum placement in inter-proximal spaces
- Use an injection-molded thermoplastic material which is then coated with a fixed amount of aluminum sulfate hexadecahydrate to help control gingival bleeding.

Intended Use of the Device

Benda Wedge is to be used in combination with other devices to temporarily retain composite or amalgam restorative material during dental restorations and to control gingival bleeding.

Technological Characteristics Compared to Predicate

Benda Wedge and the Wedge Wand predicate device have the following similar characteristics:

- Both Benda Wedge and predicate wedge device use thermoplastic material but Benda Wedge is then coated with an astringent agent to control gingival bleeding
- Astringent chosen for subject device is comparable in identity, mode of operation and amount to predicate cord device
- Available in 4 model sizes of wedge incorporating the same basic design as predicate wedge device
- Same intended use as wedge predicate device
- Same operating principle as wedge predicate device

Non-Clinical Performance Data

Biocompatibility testing was performed on the subject device in conformance with ISO 10993-1 guidelines.

Clinical Testing

Clinical testing has not been performed on this product.

Conclusion

We believe the Benda Wedge device is substantially equivalent to the Wedge Wand predicate device.

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

July 8, 2014

Centrix, Inc.
Mr. Greg Moreau
RA/QA
770 River Road
Shelton, CT 06484

Re: K140144
Trade/Device Name: Benda wedge
Regulation Number: 21 CFR 872.4565
Regulation Name: Dental Hand Instrument
Regulatory Class: I
Product Code: EJB
Dated: April 17, 2014
Received: April 22, 2014

Dear Mr. Moreau:

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,

Mary S. Runner -S

Erin I. Keith, M.S.
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

510(k) Number: K140144

Device Name: Benda Wedge

Indications for Use:

Benda Wedge is an inter-proximal wedge coated with an astringent to be used in combination with other devices to temporarily retain composite or amalgam restorative material as well as to control gingival bleeding during dental restorations.

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)

Sheena A. Green -S
2014.07.08 09:41:11 -04'00'