June 9, 2020

Bennett Jacoby, DDS, MS, Inc.
Bennett Jacoby
President
77-6425 Kuakini Hwy, C2-84
Kailua Kona, Hawaii 96740

Re: K192033
Trade/Device Name: Contour P-Insert 90, Contour P-Insert 45, Contour P-Insert Tri Tip, Contour P-Insert WC Tip, Contour P-Insert Quad Tip
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: DZI, ELC
Dated: May 6, 2020
Received: May 11, 2020

Dear Bennett Jacoby:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192033

Device Name
Contour P-Insert System (CPIS)

Indications for Use *(Describe)*
The Contour P-Insert System (CPIS) is an accessory attachment to the Dmetec Surgystar piezosurgery system. It is used by dental professionals during treatment of periodontal disease and oral surgery for the following intended uses:

1. Surgical procedures including osteotomy, osteoplasty, periodontal surgery and implantation.
2. Soft tissue debridement and removal, particularly in intrabony lesions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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4. 510(k) SUMMARY

510(k) Sponsor & Manufacturer Information	
510(k) Sponsor & Manufacturer	Bennett Jacoby, DDS, MS, Inc.
Address	77-6425 Kuakini Hwy, C2-84, Kailua-Kona, HI 96740
Telephone	731 451 0213
Email	bjacobyddsms@gmail.com
510(k) Summary Preparation Date	June 4 2020

510(k) Submitter Information	
510(k) Submitter Name	Marc Sanchez
Company Name	Contract In-House Counsel & Consultants, LLC (d/b/a FDA Atty)
Telephone	202 765 4491
Email	msanchez@fdaatty.com

Device Information	
Device Name	Contour P-Insert System
Classification Name	a) Drill, bone, powered b) Scaler, ultrasonic
Product Code	DZI, ELC
Device Classification Panel	OHT1/DHT1B (Dental Devices)
Device Classification	Class II

Predicate Devices

Predicate Device Name		Predicate Device Sponsor	Product Code	510(k) No.
Surgystar	Predicate Device	Dmetec Co. Ltd.	DZI	K113152
Diamond Coated Inserts	Reference Device 1	Dentsply International	ELC	K030111
Piezosurgery Plus	Reference Device 2	Mectorn S.p.a.	JDX, **DZI**, ERL, HBE, HWE	K153743

Device Description

The Contour P-Insert System (CPIS) is an accessory to the Dmetec Surgystar Piezosurgery System (DSPS). The CPIS comprises two sets of components, CPIS tips and CPIS shafts, as follows:

- CPIS Shafts: The two CPIS shaft models (45 and 90) are machined from 431 stainless steel. Both models have an identical female threaded proximal end that is designed and configured to attach to the DSPS handpiece distal male threaded end. On the shafts' distal end, both models have an identical male threaded section that is designed and configured to attach the various models of CPIS tips. These models

  45 and 90 differ primarily in that the CPIS 45 has a mid-shaft bend of 20.5^0 while the CPIS 90 does not.
- CPIS Tips: The three CPIS tip models (Tri, WC and QT) are machined from PEEK (polyetheretherketone). All three tip models have an identical female unthreaded hole on the proximal end that is designed and configured to attach to the distal male threaded end of the CPIS shafts. These tips have different grooves, edges and vertices that abrade, ablate, cut and recontour oral tissues as intended by the operator.
- CPIS Inserts: The CPIS inserts are created by the end user by attaching one CPIS tip to one CPIS shaft. By combining each of the three tip models with each of the two shafts models, six versions of CPIS insert can thus be created, depending on the clinical needs and professional judgement of the end-user. These resultant CPIS inserts are designated as follows: CPIS 45/Tri, CPIS 45/WC, CPIS 45/QT, CPIS 90/Tri, CPIS 90/WC and CPIS 90/QT. The CPIS inserts are attached to the DSPS using the DSPS torque wrench.

  During use by the end user, the DSPS is powered, generating high frequency mechanical micro-vibrations in the handpiece, that is transmitted to the CPIS insert. The tip sides and tip end of the CPIS inserts are brought into contact with the patient's various oral tissue types to accomplish dental procedures where ablation, abrasion, cutting and/or recontouring of the target tissue is desired.

Indications for Use

The Contour P-Insert System (CPIS) is an accessory attachment to the Dmetec Surgystar piezosurgery system. It is used by dental professionals during treatment of periodontal disease and oral surgery for the following uses:

1. Surgical procedures including osteotomy, osteoplasty, periodontal surgery and implantation.
2. Soft tissue debridement and removal, particularly in intrabony lesions.

Technological Characteristics

Characteristic	Subject Device	Predicate Device K113152	Reference Device 1 K030111	Reference Device 2 K153743
Device	Contour P-Insert System (CPIS)	Surgystar	Diamond Coated Inserts	Piezosurgery Plus
Indications for Use	**1)** Surgical procedures including osteotomy, osteoplasty, periodontal surgery and implantation. **2)** Soft tissue debridement and removal, particularly in intrabony lesions.	**1)** in surgical procedures including osteotomy, osteoplasty, periodontal surgery and implantation.	**1)** Removal of extremely tenacious deposits of calculus in both non-surgical and surgically exposed cases. **2)**Removal of overhangs and re-contouring of dental restorations (amalgam, gold, composite, acrylic and porcelain) in both non-surgical and surgically exposed cases. **3)**Soft tissue debridement – removal of tissue tags, particularly in intrabony lesions	**1)** Ultrasonic surgical system consisting of handpieces and associated tips for osteotomy, osteoplasty and drilling in a variety of surgical procedures
Compatibility & Functionality	The user assembled CPIS inserts are attached to the male thread on the distal end of the Dmetec handpiece.	The DSPS inserts are attached the male thread on the distal end of the Surgystar handpiece	NA – compatibility and functionality of the CPIS required with Predicate Device only	NA – compatibility and functionality of the CPIS required with Predicate Device only

Characteristic	Subject Device	Predicate Device K113152	Reference Device 1 K030111	Reference Device 2 K153743
Design	**Insert:** End-User assembled CPIS Inserts are created from one shaft and one tip. **Two CPIS Shaft Designs:** Rigid 431 stainless steel shaft-like piece with a distal segment angulation of 69.5 degrees (Model 45) or 90 degrees (Model 90) in relation to the long axis of the shaft. **Three CPIS Tip Designs**: Triangular, non-stepped pyramid (Model Tri) Stepped cone (Model WC) Four-sided stepped pyramid (Model QT)	The DSPS inserts do not have components – they are a single unit. DSPS metal insert with a saw-toothed distal working end with 3 sharp points. DSPS insert with a ball shaped distal working end that is coated in diamond grit.	The Diamond Coated inserts do not have components – they are a single unit. This is an industry-typical magnetostrictive scaler insert with an arch-shaped working end with the terminal distal end coated with diamond grit.	Metal inserts designed and configured to cut and drill bone.
Sterilization State	Supplied non-sterile	Supplied non-sterile	Supplied non-sterile	Supplied sterile
Sterilization Method (prior to use)	Steam Sterilization	Steam sterilization	Steam sterilization	EO sterilization
Insert Materials	**Shaft:** 431 Stainless Steel **Tip** PEEK	Stainless Steel of unspecified type	Diamond & Nickel (known materials)	**Insert** Titanium alloy, 316/316L stainless steel, **Protective Sleeve** PEEK

Non-Clinical Test Reports - Applicable Standards

The following tests were performed on the Contour P-Insert System and the test results show that the subject device is substantially equivalent to the predicate and reference devices:

Test Name	Standard
In Vitro Cytotoxicity Test of PEEK	ISO10993-5:2009 (Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity)

Skin Sensitization Test of PEEK	ISO10993-10:2010 (Biological evaluation of medical devices — Part 10: Tests for skin sensitization)
Intracutaneous Reactivity Test of PEEK	ISO10993-10:2010 (Biological evaluation of medical devices — Part 10: Tests for skin sensitization)
Acute Systemic Toxicity of PEEK	ISO10993-11:2017 (Biological evaluation of medical devices — Part 11: Tests for systemic toxicity)
Pyrogen Test of PEEK	ISO10993-11:2017 (Biological evaluation of medical devices — Part 11: Tests for systemic toxicity)
In Vitro Hemolytic Properties Test of PEEK	ISO10993-4:2017 (Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood)
Complement Activity (C3a,SC5b-9) Test of PEEK	ISO10993-4:2017 (Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood)
Sterilization Validation (including drying validation)	ISO17665 - 1:2006 / (R)2013 (Sterilization of healthcare products – Moist Heat – Part 1 Requirements for the development, validation and routine control of a sterilization process for medical devices) ISO14937:2009 / (R)2013 (Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices) ISO11138-3:2017 (Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes) ANSI/AAMI ST79:2017 (Comprehensive guide to steam sterilization and sterility assurance is health care facilities)
CPIS Functionality and Efficacy Report	N/A - No consensus standards exist for this test. Relevant literature and the standard of care are applicable.
Tooth Surface Damage Study	N/A - No consensus standards exist for this test. Relevant literature and the standard of care are applicable.

The following tests were performed to determine the compatibility, functionality and performance of the CPIS. Five tests were performed on the subject device. As no written ISO or other consensus standards are applicable for the aforementioned tests, the peer-reviewed published literature and standard of care is cited as applicable in the study reports.

1. Test Objective: Determination if the CPIS is compatible with the predicate device DSPS torque wrench accessory.
   Outcome: The DSPS torque wrench fit, engaged, retained and easily disengaged from 100% of the CPIS samples.

Conclusion: This test demonstrates the compatibility of the DSPS torque wrench with the CPIS, and the Substantial Equivalence of the CPIS with the Predicate Device DSPS inserts due to the consistent fit of the DSPS torque wrench on the CPIS shaft square connector which is critical for proper function of the CPIS when connected to the DSPS.
Test Objective: Determination if the CPIS shaft proximal female threaded connector is compatible with the predicate DSPS handpiece distal end male threaded connector.
Outcome: No loosening of the CPIS inserts from the DSPS handpiece was observed in 100% of samples.
Conclusion: This test demonstrates the compatibility of the CPIS with the DSPS handpiece and the Substantial Equivalence of the CPIS with the Predicate Device DSPS. Specifically, the CPIS fits the Predicate Device DSPS handpiece distal male threaded connector and remains securely attached during use.

2. Test Objective: Determination if the CPIS is "as safe and effective" as the predicate (confirming SE) in performing this 510(k) submission's indications for use: soft tissue debridement and periodontal surgery
   Outcome: For all samples in all groups, soft tissue was effectively debrided to expose all intended root surfaces.
   Conclusion: This test demonstrates that the CPIS is "as safe and effective" as the predicate (confirming SE) in carrying out this 510(k) stated indications for use of "soft tissue debridement" and "periodontal surgery"; therefore, the CPIS has been shown to be Substantially Equivalent to the Predicate and Reference Devices.

3. Test Objective: Determine if the CPIS is "as safe and effective" as the predicate (confirming SE) in performing this 510(k) submission's indications for use of: osteotomy, osteoplasty and periodontal surgery.
   Outcome: For all samples in all groups, more than 1mm of bone, but less than 3mm of bone, was removed from around all Mock Resorptive Lesions as intended.
   Conclusion: This test demonstrates that the CPIS is "as safe and effective" as the predicate (confirming SE) in carrying out this 510(k) stated indications for use of "osteotomy, osteoplasty, and periodontal surgery"; therefore, the CPIS has been shown to be Substantially Equivalent to the Predicate and Reference Devices.

4. Test Objective: Determine if the CPIS PEEK tips and the DSPS inserts damage tooth surfaces.
   Outcome: In all cases, the CPIS QT PEEK tip did not cause any discernible tooth surface damage, while both DSPS inserts caused extensive tooth surface damage.
   Conclusion: This test demonstrates that the CPIS is safe for use when in contact with tooth structure while the DSPS inserts tested are not safe for use in contact with tooth structure; therefore, the CPIS is superior to the Predicate Device DSPS inserts tested.

Conclusion

The documentation demonstrates that the Contour P-Insert System (CPIS) is substantially equivalent to the predicate and reference devices. It is further concluded that the CPIS is "as safe and effective" as the predicate (confirming SE) as an accessory to the DSPS to carry out the stated indications for use of: osteotomy, osteoplasty, soft tissue debridement and periodontal surgery. These conclusions are based on the similarities in intended use, principles of operation, compatibility & functionality, and sterilization method.

Any differences in materials, design, or geometry have nominal to no impact on safety and do not raise new or different questions of efficacy as clearly demonstrated by the non-clinical studies included with this 510(k) submission.