May 25, 2023

Excelent Inc.
% Bryan Brosseau
President
Brosseau Consulting LLC
2352 Kennesaw Oaks Trl NW
Kennesaw, Georgia 30152

Re: K230258
Trade/Device Name: BB 8 Sinus Dilation Kit
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: April 25, 2023
Received: April 26, 2023

Dear Bryan Brosseau:

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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230258

Device Name
BB 8 Sinus Dilation Kit

Indications for Use *(Describe)*
To access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

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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510(k) Summary – K230258

Date Prepared:

May 23, 2023

Submitted By:

EXCELENT INC.
68 TW Alexander Drive
PO Box 13628
Research Triangle Park
Durham, NC 27709

Contact:

Name: Bryan Brosseau
Title: Consultant to EXCELENT INC.
Telephone: (404) 610-7215
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Device:

Trade Name:	BB 8 Sinus Dilation Kit
Common Name:	Sinuplasty Balloon Catheter
FDA Product Code:	LRC
Device Classification:	Class I
Classification Name:	Instrument, ENT Manual Surgical
Device Regulation:	21 CFR 874.4420

Predicate Devices:

The device is substantially equivalent to the following predicate devices:

Primary Predicate:	Entellus Xpress Multi-Sinus Dilation System, (K152434)
Secondary Predicate:	Entellus PathAssist LED Light Fiber, (K152435)

Device Description:

The BB 8 Sinus Dilation Kit is intended to remodel or recreate the sinus outflow tract via trans-nasal balloon dilation. The device combines features of a curved suction tip and a sinus ostium seeker with the tissue expansion effect of balloon dilation. Since the distal end of the device is re-shapeable, one balloon can be modified to work on multiple sinuses within the same patient. The device also allows the capability to suction and irrigate the surgical field to allow for removal of bodily secretions and to keep the field of view clean for improved visualization. The device includes an LED light with light fiber to locate, illuminate within, and transilluminate across nasal and sinus structures.

In summary, the device includes the following components and accessories:

1. BB 8 Sinus Dilation Kit which incorporates:
    a. shapeable catheter with inflatable balloon
    b. LED light fiber
    c. irrigation line, and
    d. suction line,
2. Inflation syringe,
3. Extension line used for inflation of the balloon (and to provide irrigation, if desired), and
4. A bend template for shaping the catheter tip for treating various sinus anatomy

Indications for Use:

To access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

Technological Characteristics and Performance Data (Predicate Comparison):

The device has similar intended use, indications for use, mechanism of action, and performance compared to the predicate devices.

The balloons of the EXCELENT and Entellus devices are both positioned over a shapeable catheter and are manually inflated with saline and a syringe until the desired inflation pressure (up to 12 ATM) is achieved. The subject and predicate device principles of operation are identical. Both devices are advanced into the nasal and sinus anatomy under direct endoscopic visualization and treat the anatomy by dilating and displacing anatomic structures along the sinus drainage pathways. Both devices are used through a trans-nasal approach.

The intended use, indications for use, balloon dimensions, sterilization method, maximum inflation pressure, catheter type, light feature, inflation mechanism, and biocompatibility have been demonstrated as identical or similar between the subject and predicate devices.

Additionally, verification testing for the subject device is similar to the testing performed for the predicate devices and demonstrates that minor differences in the device characteristics between the subject and predicate devices do not raise any new questions of safety and efficacy. Verification testing performed for the subject device includes:

- Visual Testing
  - Visual Connection Indicators on Device Handle
  - Marker Band Location
- Dimensional Testing
  - Catheter Shaft Working Length
  - Device Weight
  - Luer Connections
  - Distal Tip Length and Outer Diameter
  - Extension Line Length
  - Balloon Working Length
  - Balloon Outer Diameter
- Functional Testing
  - Bend Radius
  - Pliable Shaft Fatigue
  - Suction Force
  - Irrigation Rate
  - Balloon Inflation Time
  - Balloon Deflation Time
  - Balloon Fatigue Test
  - Balloon Burst Pressure
  - LED Visibility
  - LED Battery Life
  - Atraumatic Tip Joint Strength
  - Manifold Joint Strength
  - Manifold Torque Value
- Electrical Safety and EMC Testing
- Biocompatibility Testing
- Sterilization, Packaging, and Shelf-Life Testing

A comparison of technological characteristics and performance data to the predicate devices is provided in **Table 1**, below.

Table 1: Comparison to Predicate Devices

Product Characteristic	Subject Device	Primary Predicate	Secondary Predicate	Comparison of Devices
Applicant	EXCELENT INC.	Entellus Medical Inc.	Entellus Medical Inc.	N/A
Product Name	BB 8 Sinus Dilation Kit	XprESS Multi-Sinus Dilation System	Entellus PathAssist LED Light Fiber	N/A
Common Name	Balloon Sinus Dilation System	Balloon Sinus Dilation System	Sinus Guidewire	Similar, the EXCELENT device is a balloon dilation system similar to the XprESS system with an integrated LED light similar to the PathAssist LED light fiber.
Device Classification Name	Instrument, ENT Manual Surgical	Instrument, ENT Manual Surgical	Instrument, ENT Manual Surgical	Identical, all devices manual ENT surgical instruments.
510(k) Number	K230258	K152434	K152435	N/A
Classification Regulation	Class I, 874.4420	Class I, 874.4420	Class I, 874.4420	N/A
Product Code	LRC	LRC	LRC	Identical, all products are classified under the LRC product code.
Intended Use	To access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a trans-nasal approach.	To access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a trans-nasal approach.	To locate, illuminate within, and transilluminate across nasal and sinus structures.	Similar, the EXCELENT device shares the same intended use as the primary predicate and includes an LED light to illuminate the treatment area in a manner that is similar to the secondary predicate.

Product Characteristic	Subject Device	Primary Predicate	Secondary Predicate	Comparison of Devices
Indications for Use	To access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.	To access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older using a transnasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.	To locate, illuminate within, and transilluminate across nasal and sinus structures.	Similar, the Indications for Use of the subject and predicate device are identical. The use of the LED feature of the subject device is similar to the indications for use of the secondary predicate device. The integrated LED light of the subject device allows the user to confirm the positioning of the balloon using the transillumination technique prior to inflating the balloon.
Sterility	Sterile (EtO)	Sterile (EtO)	Sterile (EtO)	Identical, all products are provided sterile and are sterilized via EtO.
Type of Use	Single-Patient Use, Prescription (Rx only)	Single-Patient Use, Prescription (Rx only)	Single-Patient Use, Prescription (Rx only)	Identical, all devices are single-patient use and prescription only.
Balloon Diameter and Length	6mm (diameter) x 20mm (length)	6mm (diameter) x 20mm (length) (XpreSS Ultra Configuration)	N/A	Identical, the subject device balloon dimensions are identical to one configuration of the primary predicate device.
Distal Tip Diameter	1.95 mm	1.5 mm (XprESS Ultra Configuration)		Similar, the distal tip diameter of the subject device is within the range of distal tip diameters for the predicate device.

Product Characteristic	Subject Device	Primary Predicate	Secondary Predicate	Comparison of Devices
		1.75 mm (XprESS LoProfile Configuration) 2.0 mm (XprESS Pro Configuration		
Maximum Balloon Inflation Pressure	12 ATM	12 ATM	N/A	Identical, the maximum balloon inflation pressure is identical to the primary predicate device.
Catheter Type	Flexible, shapeable, with atraumatic tip, irrigation and suction features	Flexible, shapeable, with atraumatic tip, irrigation and suction features	N/A	Similar, the catheter portion of the subject and primary predicate devices is shapeable for use in multiple sinuses. Both devices incorporate irrigation and suction. Both devices are provided with a bending tool to provide the proper bend for each sinus.
Light Source	Light delivered via fiber optic from an integrated, battery powered, LED light source with > 60 minutes battery life	N/A	Light delivered via fiber optic from an integrated, battery powered, LED light source with > 60 minutes battery life	Similar, both the subject device and the secondary predicate provide illumination from a similar electronic component. The integration of the LED light system in the subject device does not raise any new questions of safety or efficacy.
Inflation Mechanism	The inflation syringe is provided with the system and the incorporated pressure gauge provides a visual scale of pressure in 1 ATM increments with even increments labeled on the pressure gauge (2,	The inflation syringe is provided with the system and provides a visual indicator when 12 ATM balloon pressure is achieved (via alignment of syringe marking and distal syringe seal).	N/A	Similar, both inflation mechanisms provide a visual indication of balloon pressure to allow the user to pressurize to the maximum pressure of 12 ATM.

Product Characteristic	Subject Device	Primary Predicate	Secondary Predicate	Comparison of Devices
	4, 6, etc. and including 12 ATM).			
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Similar, the subject device has undergone biocompatibility testing in accordance with ISO 10993-1 based on the intended nature and duration of contact.

Conclusions:

The subject device and the predicate devices underwent evaluation that confirms equivalence in the intended use of each device, biocompatibility, performance, environment of use, and the principles of operation. Therefore, the subject device is deemed substantially equivalent to the predicate devices.