December 20, 2018

3NT Medical Ltd.
% Orly Maor
Company Regulatory Consultant
25 Sirkin Street
Kfar Saba 44421, Israel

Re: K181838
Trade/Device Name: Sinusway Dilation System
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, And Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: November 28, 2018
Received: November 28, 2018

Dear Orly Maor:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
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)*
K181838

Device Name
Sinusway Dilation System

Indications for Use *(Describe)*
The Sinusway Dilation System is intended to access and treat the frontal, maxillary and sphenoid sinuses in sinus procedures in adults using a trans-nasal approach, by dilation and displacement of the anatomic structures along the sinus drainage pathways.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional Premarket Notification Submission – 510(k)
Sinusway Dilation System
510(k) Number K181838

Date Prepared: December 13, 2018

I. SUBMITTER

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II. DEVICE

Name of Device: Sinusway Dilation System
Common or Usual Name: Sinusway Dilation System
Classification Name: Ear, nose, and throat manual surgical instrument (21 CFR 874.4420)
Regulatory Class: I (510(k) exempt)
Product Code: LRC

III. PREDICATE DEVICE

3NT Medical Ltd. believes that the Sinusway Dilation System is substantially equivalent to the following predicate device cleared under multiple clearances:

- Entellus Medical Inc. XprESS Multi-Sinus Dilation Tool cleared under K102003, K112506 and K121174, Product code LRC.

IV. DEVICE DESCRIPTION

Sinusway Dilation System combines the tissue expansion effect of balloon dilation with the features of a curved sinus seeker, and by that allows the user to track the dilation device into the sinus drainage pathways. The shape of the distal end of the dilation system can be changed by inserting pre-shaped seekers into it. The system includes:

1. A Dilation Kit (Single use, provided sterile) consists of the following components:
   a. A Dilation Device – includes an inflatable balloon at its distal end and connects to the inflation device at its proximal end.
   b. Three interchangeable pre-shaped Seekers (also referred to as stylets).
   c. An Inflation Device – connects to the dilation device and inflates it while providing visual and tactile pressure indication.

   All Dilation Kit components are disposed of at the end of the procedure.
2. A Holder (re-processible and auto-clavable) – holds the components of the Dilation Kit in place and locks them, allowing the user to operate the dilation tool.

V. INDICATIONS FOR USE

Sinusway Dilation System is intended to access and treat the frontal, maxillary and sphenoid sinuses in sinus procedures in adults using the trans-nasal approach, by dilation and displacement of the anatomic structures along the sinus drainage pathways.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Sinusway Dilation System has the same intended use and indications for use as the Entellus predicate device. Sinusway Dilation System, same as the predicate device, use balloon dilation technology to access and treat the target anatomy. Both balloons are positioned over a rigid pre-shaped seeker and are manually inflated with saline until the desired result is achieved. The Sinusway Dilation System and Entellus 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.

Similar tests and tests methods performed in accordance with the same standards were used in both Sinusway Dilation System and the predicate device to validate the design. The testing results showed that the minor differences in device characteristics and principles of operation between the subject device and predicate device do not raise any new questions of safety or effectiveness.

The Sinusway Dilation System has the same technological characteristics as the predicate devices as demonstrated in the table below:

Name	3NT Medical Sinusway Dilation System	Entellus Medical XprESS Multi-Sinus Dilation Tool	SE Justification
510(k) number	K181838	K102003 and subsequent K112506 and K121174	
Product Code	LRC	LRC	Same
CFR	Class I, 21 CFR 874.4420	Class I, 21 CFR 874.4420	Same
Indications for Use	Intended to access and treat the frontal, maxillary and sphenoid sinuses in sinus procedures in adults, by dilation and displacement of the anatomic structures along the sinus drainage pathways.	Intended to access and treat the frontal recesses, sphenoid sinus ostia, maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinuses structure.	Same
Balloon Diameter	6mm	5mm, 6mm, 7mm	Same The 3NT size is included within the predicate range of sizes
Balloon Length	10mm	8mm, 18mm	SE The 3NT size is included within the predicate range of sizes
Distal Ball Tip Diameter	1.5mm	2mm	SE
Dilation Device Angles	Similar to sinus seekers, pre-set by replaceable pre-bent seekers	Similar to sinus seekers, pre-set by bending a shapeable seeker	SE
Guided by Direct Visualization?	Yes	Yes	Same
Trans-Nasal Approach?	Yes	Yes	Same
Inflation device	Syringe barrel and plunger based	Syringe barrel and plunger based	Same

Name	3NT Medical Sinusway Dilation System	Entellus Medical XprESS Multi-Sinus Dilation Tool	SE Justification
Balloon inflation substance	Saline	Saline	Same
Pressure Indication	Visual and tactile	Visual only	SE
Rated Burst Pressure	17.4 atm	19-22 atm (6mm balloon)	Similar, both are above the maximal inflation pressure
Dilation Tool Sterilization	EtO (single-use)	EtO (single-use)	Same
Biocompatibility	All surfaces which come in contact with the patient's mucosal surfaces were successfully tested for biocompatibility in accordance with ISO 10993-1.	All surfaces which come in contact with the patient's mucosal surfaces were successfully tested for biocompatibility in accordance with ISO 10993-1.	Same
Prescription Use	The device should be used only by trained surgeon under a physician order.	The device should be used only by trained surgeon under a physician order.	Same

Based on the above analysis, 3NT Medical Ltd. believes that the Sinusway Dilation System is substantially equivalent to the legally marketed predicate devices

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- **Risk analysis** per ISO 14971:2012
- **Biocompatibility testing**

  An evaluation of biocompatibility was performed in compliance with ISO 10993-1. Biocompatibility evaluation included cytotoxicity, irritation, sensitization and acute systemic cytotoxicity testing. All tests were completed with passing results.
- **Sterilization, Packaging and Shelf Life Testing**

  Sterilization validation testing of the endoscope was performed to demonstrate compliance with ISO 11135-1. The handle was validated for cleaning and re-use by autoclave. In addition, shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.

- **Bench Testing**

  Bench testing included the following:

  - Balloon Dilation Tool Fatigue
  - Inflation/Deflation time test protocol
  - Visual and demonstration Report
  - Dimensional Attribute
  - Compliance (Diameter vs. Pressure) Report
  - Balloon Rated Burst Pressure Report
  - Bond Strength Report
  - Inflation Mechanism - Pressure feedback range testing Report
  - Functionality and simulated use

  All tests met the predefined acceptance criteria.

VIII. CONCLUSIONS

The Sinusway Dilation System has the same intended use as the predicate device. The principal features of the device that were described, as well as the testing provided, show that the minor differences in device characteristics between the subject device and predicate device do not raise any new questions of safety or effectiveness.
Performance data has been provided, establishing that the Sinusway Dilation System performs as intended and in a manner that is substantially equivalent to the predicate.
Therefore, the device may be found substantially equivalent.