December 12, 2017

M/s. Meril Life Sciences Private Limited
Umesh Sharma
General Manager - Quality Assurance/Regulatory Affairs
Survey No. 135/139, Bilakhia House, Muktanand Marg
Chala, Vapi, 396191 Gujarat
India

Re: K172737
Trade/Device Name: MESIRE™ - Balloon Sinus Dilatation System
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, And Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: September 7, 2017
Received: September 11, 2017

Dear Umesh Sharma:

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.

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.

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 yours,

Eric A. Mann -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)*
K172737

Device Name
MESIRE(TM) - Balloon Sinus Dilatation System

Indications for Use *(Describe)*
MESIRE™ - Balloon Sinus Dilatation System is intended to provide a means to access the sinus space and to dilate the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures.
For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

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

I. Submitter

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Contact Person: Umesh Sharma
Date Prepared: November 20th, 2017

II. Device

Trade / Proprietary Name	Regulatory Class	Product Code	Regulation Number	Review Panel
MESIRE™ – Balloon Sinus Dilatation System	I	LRC	21 CFR 874.4420	Ear, Nose, and Throat Manual Surgical Instrument

III. Predicate Device

- Relieva Solo Elite™ Sinus Balloon Catheter **(510k no. K111254)**
- Relieva Ultirra™ Nav Sinus Balloon Catheter **(510k no. K161698)**

IV. Device Description

The **MESIRE™** – Balloon Sinus Dilatation System consists of following components. It is available as an integrated system or individual components.

1. **MESIRE™** Sinus Balloon Catheter
2. **MESIRE™** Guide - Sinus Guide Catheter
3. **MESIRE™** Illuminus – Sinus Light Wire
4. **MESIRE™** Latch - Catheter Holding System

1. MESIRE™ Sinus Balloon Catheter

MESIRE™ Sinus Balloon Catheter is an “Over the Wire” type catheter with an integrated shaft system and a low profile Pebax balloon (dilatation element) which is bonded distally to the inner lumen and proximally to outer lumen with distal shaft. The system has dual lumen one lumen is used for inflation of the balloon with saline, and second provides passage of sinus light wire to facilitated advancement of the sinus balloon catheter to the target.

The proximal end of inner lumen is assembled to a Luer hub at its proximal end. The distal shaft, hypo tube, strain relief (protect from bending and kinking) are bonded to the hub from the proximal end of the hub respectively. The main port of Hub permits the use of guide wire and Lateral port for balloon inflation / deflation. Three distal endoscopic markers present on the distal shaft of the Sinus balloon catheter helps in accurate positioning of the balloon under endoscopy.

Three proximal shaft markers present on the hypo tube helps in positioning the Sinus balloon catheter with respect to Sinus Guide catheter. The first proximal shaft marker at distal end on hypo tube indicated that the tip of the Sinus balloon catheter is in the straight section of the sinus guide catheter. Second and third proximal shaft markers on hypo tube correspond to the exit of the balloon from the sinus guide catheter.

2. MESIRE™ Guide - Sinus Guide Catheter

The MESIRE™ Guide - Sinus Guide Catheter consists of a distal angled tip, a SS shaft and a proximal luer hub. A blue marker tip allows endoscopic visualization. The shaft consists of a stainless steel tube and a lubricious PTFE inner liner. Tip angle is mentioned on color band. The Luer hub allows for flushing of the device before use.

The MESIRE™ Guide - Sinus Guide Catheter is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures.

3. MESIRE™ Illuminus – Sinus Light Wire

The MESIRE™ Illuminus – Sinus Light Wire–is 0.83 mm compatible flexible light wire that transmits light from the proximal to distal tip. The MESIRE™ Illuminus – Sinus Light Wire consists of a light guide cable connector, Stainless steel coil wire, fiber optic cable and a distal and proximal light lens.

The light guide cable connector is an universal connector and it is to be attached with light cable (Available with Health care facility) and light cable is further connected with light source (Available with Health care facility). When light source is put on the proximal light lens will pass the light through and distal light lens will illuminate.

The MESIRE™ Illuminus – Sinus Light Wire is intended to provide a means to access the sinus space for diagnostic and therapeutic procedures in conjunction with other nasal and sinus products. It is also intended to illuminate within and transilluminate across nasal and sinus structures.

4. MESIRE™ Latch - Catheter Holding System

The MESIRE™ Latch - Catheter Holding System is attached to the proximal end of sinus guide catheter. The projection of Catheter Holding System to the sinus guide catheter provides an augmentation to the users to sustain the position of Sinus guide catheter. MESIRE™ Latch - Catheter Holding System is compatible with minimum Sinus guide catheter ID 2.50mm

The MESIRE™ Latch - Catheter Holding System is intended to provide an augmentation to sinus guide catheter.

V. Intended Use

MESIRE™ – Balloon Sinus Dilatation System is intended to provide a means to access the sinus space and to dilate the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures.

For children aged 17 and under, the balloon catheter system is intended to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.

VI. Substantial Equivalence

The MESIRE™ – Balloon Sinus Dilatation System is substantially equivalent to marketed predicate devices with respect to intended use and technological characteristics. The MESIRE™ –Sinus Balloon catheter operates on the same principle as predicate devices i.e. hydraulic pressurization applied through an inflatable balloon attached to the distal end.

Comparison Chart of MESIRE™ – Balloon Sinus Dilatation System and Predicate devices

Characteristics	Subject Device	Predicate Device	
Device Name	Mesire™ Balloon Sinus dilatation System	Relieva Solo Elite™ Sinus Balloon Catheter	Relieva Ultirra™ Nav Sinus Balloon Catheter
510 (K) Number	K172737	K111254	K161698
Manufacturer	Meril Life Sciences Pvt. Ltd., India	Acclarent Inc.	Acclarent Inc.
Common Name	Sinus Balloon Dilation System	Sinus Balloon Dilation System	Sinus Balloon Dilation System
Class	I	I	I
Product Code	LRC	LRC	LRC
Regulation Number	21 CFR 874.4420	21 CFR 874.4420	21 CFR 874.4420
Single Patient Use	Yes	Yes	Yes
Direct Patient Contact	Yes	Yes	Yes
Principles of Operation	Hydraulic pressurization applied through an inflatable	Hydraulic pressurization applied through an inflatable	Hydraulic pressurization applied through an inflatable

	balloon	balloon	balloon
Balloon Diameter	5mm, , 6mm, 7mm	3.5mm, 6mm, 7mm	5mm
Balloon Length	17mm	16mm	16mm
Working Length	256mm	245 mm	245 mm
Maximum Inflation Pressure	13-14 ATM	12 ATM	12 ATM
Flexible Shaft	Yes	Yes	Yes
Indications for Use	Dilation of Sinus Tissue	Dilation of Sinus Tissue	Dilation of Sinus Tissue
Technological Characteristics	Enables dilation of sinus ostia	Enables dilation of sinus ostia with added capability of irrigating the sinuses.	Allows for dilation of sinus ostia and EM Navigation
Use a Sinus Guide for Access into Targeted Anatomy	Yes	Yes	Yes
Guidewire Compatibility with Sinus Illumination System	Yes 0.89 mm (0.035”)	Yes 0.035”	Yes 0.035”
Sterilisation	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Biocompatibility	Complies with ISO 10993	Complies with ISO 10993	Complies with ISO 10993

VII. Performance Data

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

Mechanical Tests

Simulated use testing was performed utilizing the Mesire™ Balloon Sinus dilatation System components. The following testing demonstrated that Mesire™ Balloon Sinus dilatation System effectively dilated the sinus.

- Visual Inspection
- Dimensional Measurement
- Balloon Burst and Balloon Compliance
- Balloon Fatigue
- Inflation and Deflation Time
- Refoldability
- Catheter Bond Strength
- Flexibility and Kink
- Freedom from leakage

Biocompatibility

The biocompatibility evaluation for Mesire™ Balloon Sinus dilatation System was conducted in accordance with FDA Bluebook Memorandum #G95-1 "Use of International standard ISO 10993, under biological evaluation of medical devices Part 1: Evaluation and testing" May 1, 1995, and International Standards ISO 10993-1 "Biological evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process" as recognized by FDA.

As per ISO 10993-1, MESIRE™ Balloon Sinus Dilatation System is a surface contacting device having contact with mucous membrane for < 24 hours. Accordingly, following biological evaluation tests were conducted:

1. Cytotoxicity
2. Sensitization
3. Irritation / Intracutaneous reactivity

Sterilisation

The sterilization process has been validated per AAMI/ANSI/ISO 11135 and demonstrated a sterility assurance level of 10^{-6}. The method used for sterilization validation was the overkill (half-cycle approach) in a fixed chamber. Ethylene oxide residuals were tested and met ISO 10993-7 requirements.

Packaging & Shelf life

Following packaging and shelf life study was conducted to ensure package integrity throughout the shelf life.

- Packaging validation as per ISO 11607
- Shelf life validation as per ASTM 1980 & ISO 11607
- Transportation Study as per ASTM D 999 & ASTM D 5276

VIII. Conclusion

MESIRE™ – Balloon Sinus Dilatation System is substantially equivalent to currently marketed devices and presents no substantial differences in design, intended use, function and technological characteristics to predicate device.

The Mechanical, Biocompatibility, Sterilisation, Packaging and Shelf life study conducted on MESIRE™ – Balloon Sinus Dilatation System demonstrated its safety, efficacy and equivalence with the predicate device.

Hence, MESIRE™ – Balloon Sinus Dilatation System will perform as intended and specified use conditions.