DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 13, 2017

Acclarent, Inc.
James Patrick Garvey II
Associate Director, Regulatory Affairs
33 Technology Drive
Irvine, California 92618

Re: K171687
Trade/Device Name: Relieva SpinPlus® Nav Balloon Sinuplasty System
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: LRC
Dated: June 6, 2017
Received: June 7, 2017

Dear James Patrick Garvey:

This letter corrects our substantially equivalent letter of September 5, 2017.

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 Industry and Consumer Education (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

Eric A. Mann -S

for Malvina 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171687

Device Name
RELIEVA SPINPLUS NAV Balloon Sinuplasty System

Indications for Use *(Describe)*
The Relieva SpinPlus Nav™ Balloon Sinuplasty System is intended to provide a means to access the sinus space within and across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

For children aged 17 and under, the Relieva SpinPlus Nav™ Balloon Sinuplasty System is intended to provide a means to access the sinus space, within and across nasal and sinus structures; dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures; and irrigate from within the maxillary sinus for therapeutic procedures and to facilitate diagnostic procedures.

The Relieva SpinPlus Nav™ Balloon Sinuplasty System may be utilized in conjunction with the ACCLARENT® ENT Navigation System, to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy

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.

510(K) SUMMARY

510(k) Number: K171687

[807.92(a)(1)] Submitter Information

Sponsor/Submitter: Acclarent, Inc.
33 Technology Drive
Irvine, CA 92618

Contact Person: Patrick Garvey
Associate Director, Regulatory Affairs
Email: pgarvey@its.jnj.com
Tel: 949-789-8505 Fax: 650-687-5899

Date Summary Prepared: August 28, 2017

[807.92(a)(2)] Name of Device

Device Trade Name: RELIEVA SPINPLUS® NAV Balloon Sinuplasty System

Common Name: Sinus Balloon Catheter

Device Classification: Class I

Regulation Number: 21 CFR 874.4420

Classification Name: Ear, Nose, and Throat Manual Surgical Instrument (21 CFR 874.4420)

Product Code: LRC

[807.92(a)(3)] Legally Marketed Devices

Predicate Devices: RELIEVA SPINPLUS® Balloon Sinuplasty System, (K143541)

Reference Devices ACCLARENT® NAVWIRE™ Sinus Navigation System, (K161697)
Medtronic NuVent™ EM Sinus Dilation System, (K152121)

[807.92(a)(4)] Device Description

Device Description: The RELIEVA SPINPLUS® NAV Balloon Sinuplasty System is packaged with a handle with integrated flexible balloon catheter and Sinus Navigation Guidewire, and three RELIEVA® Spin Sinus Guide Catheter Tips. The system features a handle with an integrated flexible balloon catheter. Features of the handle include a sinus guide tip release button, a suction system, a balloon guard, and several gripping features to grip the device. The guide tip release button must be depressed to separate the sinus guide catheter tip from the handle system. The suction system consists of a suction line and a suction port. Suction may be used to clear the field of fluids and/or blood. The suction line is attached to the proximal end of the handle system and may be removed

if desired. The suction port may be covered by the user's finger to increase the suction flow rate. A clear balloon guard is connected to the distal end of the handle system and protects the sinus balloon during sinus guide catheter tip exchanges.

The Handle features a wire slider, wire spinner, balloon slider, sinus balloon, handle markers, and proximal connections. The wire slider allows the user to advance, retract and spin the sinus navigation guidewire with a single hand while simultaneously supporting the handle. The balloon slider allows the user to advance and retract the sinus balloon catheter to the target sinus ostia and outflow tract, to enable dilation. The integrated connector enables the device to be interfaced to the ACCLARENT ENT™ Navigation System to facilitate EM navigation

The RELIEVA SPINPLUS® NAV Balloon Sinuplasty System may be utilized in conjunction with the ACCLARENT ENT™ Navigation System to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy via electromagnetic navigation.

[807.92(a)(5)] Intended Use

Indications for Use:

The RELIEVA SPINPLUS® NAV Balloon Sinuplasty System, is intended to provide a means to access the sinus space within and across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

For children aged 17 and under, the RELIEVA SPINPLUS® NAV Balloon Sinuplasty System is intended to: provide a means to access the sinus space, within and across nasal and sinus structures; dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures; and irrigate from within the maxillary sinus for therapeutic procedures and to facilitate diagnostic procedures."

The RELIEVA SPINPLUS® NAV Balloon Sinuplasty System may be utilized in conjunction with the Acclarent ENT Navigation System, to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy.

Difference in Indications from Predicate Device

The difference in indications for use between the subject and predicate devices is supported is presented in Table 1 of this summary.

[807.92(a)(6)] Technical Characteristics	
Technological Characteristics:	The RELIEVA SPINPLUS® NAV Balloon Sinuplasty System combines a Sinus Guide Catheter and Handle Assembly (integrated with Sinus Balloon Catheter, Sinus Irrigation and Electromagnetically-trackable Guidewire) into a single device. See Table 1 for a comparison of the technological characteristics between the RELIEVA SPINPLUS® NAV Balloon Sinuplasty System and the predicate devices.

Table 1: Comparison of Technological Characteristics between the RELIEVA SPINPLUS® NAV Balloon Sinuplasty System and predicate and reference devices.

Attribute	Primary Predicate Device (RELIEVA SPINPLUS® Balloon Sinuplasty System)	Reference Device (ACCLARENT NAVWIRE™ Sinus Navigation Guidewire)	Reference Device (NuVent EM Sinus Dilation System)	Subject Device (RELIEVA SPINPLUS® NAV Balloon Sinuplasty System)
510(k) number	K143541	K161697	K152121	TBD
Manufacturer	Acclarent	Acclarent	Medtronic	Acclarent
Trade Name	RELIEVA SPINPLUS® Sinus Dilation System	ACCLARENT NAVWIRE™ Sinus Navigation Guidewire	NuVent™ EM Sinus Dilation System	RELIEVA SPINPLUS® NAV Balloon Sinuplasty System
Common Name	Sinus Dilation System	Sinus Balloon Catheter	Sinus Balloon Catheter	Sinus Dilation System
Class	I	II	I	I
Product Code	LRC	PGW	LRC	LRC
Classification Section	21 CFR 874.4420	21 CFR 882.4560	21 CFR 874.4420	21 CFR 874.4420

Indications for Use	The RELIEVA SPINPLUS™ Balloon Sinuplasty System is intended to: provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures. For children aged 17 and under, the RELIEVA SPINPLUS™ Balloon Sinuplasty System is intended to: provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures; and irrigate from within the maxillary sinus for therapeutic procedures and to facilitate diagnostic procedures.	The ACCLARENT® NAVWIRE™ Sinus Navigation Guidewire is intended for use as a navigable guidewire to provide access to nasal and sinus spaces, and confirmation of placement in the accessed anatomy. The Acclarent NavWire is designed for use during procedures where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, can be identified relative to a CT-based model of the anatomy.	The EM Sinus Dilation System is intended for use in conjunction with the Medtronic Computer Assisted Surgery System during sinus procedures when surgical navigation or image-guided surgery may be necessary. When used concomitantly, these systems may be used to locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses to facilitate dilation of the sinus ostia; or locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses that is scarred, granulated or previously surgically altered to facilitate dilation of the sinus ostia. The Medtronic computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT- or MR-based model, or digitized landmarks of the anatomy. The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgment.	The RELIEVA SPINPLUS™ Nav Balloon Sinuplasty System is intended to provide a means to access the sinus space, within and across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures. For children aged 17 and under, the RELIEVA SPINPLUS™ Nav Balloon Sinuplasty System is intended to provide a means to access the sinus space, within and across nasal and sinus structures; dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures; and irrigate from within the maxillary sinus for therapeutic procedures and to facilitate diagnostic procedures. The RELIEVA SPINPLUS™ Nav Balloon Sinuplasty System may be utilized in conjunction with the ACCLARENT® ENT Navigation System, to provide access to nasal and sinus spaces, and to confirm placement in the accessed anatomy.”

Attribute	Primary Predicate Device (RELIEVA SPINPLUS® Sinus Dilation System)	Reference Device (ACCLARENT NAVWIRE™ Sinus Navigation Guidewire)	Reference Device (NuVent EM Sinus Dilation System)	Subject Device (RELIEVA SPINPLUS® NAV Balloon Sinuplasty System)
Sterilization	EtO	EtO	EtO	EtO
Packaging	Thermoformed tray in pouch	Thermoformed tray in pouch	Unknown	Thermoformed tray in pouch
Single Use	Yes	Yes	Yes	Yes
Patient Contact	Direct	Direct	Direct	Direct
Labeled as Non-Pyrogenic?	No	No	No	No
Technological Characteristics	Combines a Sinus Guide Catheter and Handle Assembly (integrated with Sinus Balloon Catheter, Sinus Irrigation and Sinus Illumination System) into a single device. The device is connected to any standard light source via accessory light cable and adapter.	The ACCLARENT® NAVWIRE™ Sinus Navigation Guidewire utilizes electromagnetic image-guided sinus surgery and is used in conjunction with a compatible surgical navigation system which consists of computer-aided software, CT-imaging, patient tracker, registration probe, and various instruments used in sinus surgery. ACCLARENT® NAVWIRE™ Sinus Navigation Guidewire provides real-time tracking at the distal tip of the guidewire in the nasal anatomy.	Combines a Sinus Guide Catheter and Handle Assembly (integrated with Sinus Balloon Catheter and Sinus Navigation System) into a single device. The device is connected to the Medtronic Fusion Navigation System to provide location information via EM navigation relative to a pre-loaded scan.	Combines a Sinus Guide Catheter and Handle Assembly (integrated with Sinus Balloon Catheter, Sinus Irrigation and Sinus Navigation System) into a single device. The device is connected to the Acclarent ENT Navigation System to provide location information via EM navigation relative to a pre-loaded scan.
Balloon Length	16 mm	N/A	17 mm	16 mm
Guidewire Diameter	0.035 inches	0.035 inches	N/A	0.035 inches
Maximum Inflation Pressure	12 ATM	N/A	Unknown	12 ATM
Flexible Balloon Catheter	Yes	N/A	N/A	Yes

Attribute	Primary Predicate Device (RELIEVA SPINPLUS® Sinus Dilation System)	Reference Device (ACCLARENT NAVWIRE™ Sinus Navigation Guidewire)	Reference Device (NuVent EM Sinus Dilation System)	Subject Device (RELIEVA SPINPLUS® NAV Balloon Sinuplasty System)
Balloon Radiopaque Marker Bands	No	N/A	EM-Navigation	No
Suction Incorporated	Yes	No	No	Yes
Irrigation Incorporated	Yes	No	No	Yes
Balloon Slide Mechanism	Yes	No	No	Yes
Indicated for Children	Yes, maxillary	Yes, maxillary[1]	No	Yes, maxillary
Compatible with ACCLARENT® ENT Navigation System	No	Yes	No (Compatible with Medtronic Fusion® ENT Navigation System)	Yes
Principles of Operation	Manually operated device. Balloon inflated with sterile saline or water to mechanically dilate sinus ostia.	Manually operated device. Balloon inflated with sterile saline or water to mechanically dilate sinus ostia.	Manually operated device. Balloon inflated with sterile saline or water to mechanically dilate sinus ostia.	Manually operated device. Balloon inflated with sterile saline or water to mechanically dilate sinus ostia.
Flexible	Yes – flexible sinus balloon catheter and guidewire.	Yes – Flexible guidewire	No- fixed, rigid instrument not designed to bend.	Yes – flexible balloon sinus catheter and guidewire.

[1] Based upon use with Relieva UltirraNav Sinus Balloon Catheter, cleared on K161698

[807.92(b) (1)] Determination of Substantial Equivalence	
Non-Clinical Performance Data:	The RELIEVA SPINPLUS Nav™ Balloon Sinuplasty System met all performance acceptance criteria including dimensional specifications; balloon burst pressure, joint separation force, deflation time, and balloon cycle fatigue. Additional testing to demonstrated that wire stiffness, tensile strength and irrigation testing were also performed to demonstrate that the device met performance specifications. Packaging shelf life was established through accelerated aging via ASTM F1980-07, ASTM F88/F88M-09, and ASTM F2096-04 requirements and confirmed to meet a shelf life of three months. Biocompatibility testing successfully completed to determine that the RELIEVA SPINPLUS® NAV Balloon Sinuplasty System is biocompatible. The sterilization process has been validated per AAMI/ANSI/ISO 11135:2014 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 10993-7:2008 requirements. The subject device is not tested nor labeled as "non-pyrogenic". Simulated use testing was performed with ENT surgeons performing balloon dilation of the paranasal sinuses utilizing the RELIEVA SPINPLUS® NAV Balloon Sinuplasty System and the ACCLARENT ENT™ Navigation System. The testing demonstrated that the RELIEVA SPINPLUS® NAV Balloon Sinuplasty System and the ACCLARENT ENT™ Navigation System could effectively access the paranasal sinuses. Clinical data was not necessary for the RELIEVA SPINPLUS® NAV Balloon Sinuplasty System. Testing was performed to verify the navigation accuracy of the device when used with the Acclarent ENT Navigation System (K161701). Testing included sensitivity and connection verification. The performance data demonstrated that the device performs as intended.

[807.92(b) (2)] Determination of Substantial Equivalence	
Clinical Performance Data	Clinical data was not necessary for the RELIEVA SPINPLUS Nav™ Balloon Sinuplasty System. The performance data demonstrated that the device performs as intended.

[807.92(b) (3)] Conclusion	
Conclusion from Non-Clinical and Clinical Tests	The RELIEVA SPINPLUS Nav™ Balloon Sinuplasty System is substantially equivalent to the predicate devices.