K183090: 510(K) SUMMARY

[807.92(a)(1)] Submitter Information

Sponsor/Submitter: Acclarent, Inc.
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[807.92(a)(2)] Name of Device

Device Trade Name:	RELIEVA TRACT™ Balloon Dilation System
Classification Name:	Ear, nose, and throat manual surgical instrument
Common Name:	Balloon, Nasal Airway
Device Classification:	Class I
Regulation Number:	21 CFR 874.4420
Review Panel:	Ear, Nose, and Throat
Product Code:	QGK

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

Predicate Device: ENT manual surgical instruments (21 CFR 874.4420)

Reference Device: RELIEVA Solo Elite™ Sinus Guide Catheter (K111254)
(trade name is RELIEVA ULTIRRA® Sinus Balloon Catheter)

Airway Balloon Catheter and Accessories (K090660)
(trade name is INSPIRA AIR® Balloon Dilation System)

[807.92(a)(4)] Device Description

Device Description: The RELIEVA TRACT™ Balloon Dilation System is a single-use, sterile device, which is intended to provide increased intranasal space to facilitate access for endonasal and transnasal procedures and/or temporarily address nasal obstruction by displacing the inferior turbinate and lower nasal septum. It is intended for use in ages 17 years or older. The RELIEVA TRACT™ Balloon Dilation System is composed of:

- A RELIEVA TRACT™ Balloon Catheter, which consists of an integrated shaft system and a high-pressure balloon near the distal tip. The shaft is a coaxial catheter. The outer lumen is used for inflation of the balloon with sterile water or saline via the ACCLARENT® Balloon Inflation Device (K090660). The inner lumen permits the use of the RELIEVA TRACT™ Stylet to facilitate advancement of the balloon catheter to the target location, such as the nasal passage in the region of the inferior turbinate and nasal septum. The proximal end of the RELIEVA TRACT™ Balloon Catheter consists of a luer that is used for inflation of the balloon and a secondary luer that is used for stylet access. The balloon is inflated by injecting sterile water or saline through the inflation luer.
- A RELIEVA TRACT™ Stylet, which is an optional accessory and intended to facilitate advancement of the Balloon Dilation Catheters. The proximal end has a luer connector that allows the stylet to lock into the stylet port of the balloon catheter. The distal end consists of an atraumatic tip.

[807.92(a)(5)] Intended Use

Indications for Use:	The RELIEVA TRACT™ Balloon Dilation System is an instrument intended to provide increased intranasal space to facilitate access for endonasal and transnasal procedures and/or temporarily address nasal obstruction by displacing the inferior turbinate and lower nasal septum. The RELIEVA TRACT™ Balloon Dilation System is intended for use in ages 17 years or older.
Difference in Indications from Predicate Device	The difference in indications for use between the subject device and the predicate/reference devices is supported is presented in Table 1 of this summary.

[807.92(a)(6)] Technical Characteristics

Technological Characteristics:	See Table 1 for a comparison of the technological characteristics between the subject device and the predicate/reference devices.

Table 1: Comparison of Technological Characteristics between RELIEVA TRACT™ Balloon Dilation System and Predicate and Reference devices.

Attribute	Predicate Device ENT Manual Surgical Instrument (21 CFR 874.4420)	Reference Device RELIEVA Solo Elite™ Sinus Guide Catheter (Ultirra) (K111254)	Reference Device Airway Balloon Catheter and Accessories (Inspira Air) (K090660)	Subject Device RELIEVA TRACT™ Balloon Dilation System
510(k) number	510(k) exempt	K111254	K090660	K183090
Manufacturer	N/A	Acclarent, Inc.	Acclarent, Inc.	Acclarent, Inc
Trade Name	N/A	RELIEVA ULTIRRA® Sinus Balloon Catheter	INSPIRA AIR® Balloon Dilation System	RELIEVA TRACT™ Balloon Dilation System
Classification Name	Ear, nose, and throat manual surgical instrument	Ear, nose, and throat manual surgical instrument	Bronchoscope (flexible or rigid) and accessories	Ear, nose, and throat manual surgical instrument
Class	I	I	II	I
Product Code	LRC	LRC	KTI	QGK
Classification Section	21 CFR 874.4420	21 CFR 874.4420	21 CFR 874.4680	21 CFR 874.4420

Attribute	Predicate Device ENT Manual Surgical Instrument (21 CFR 874.4420)	Reference Device RELIEVA Solo Elite™ Sinus Guide Catheter (Ultirra) (K111254)	Reference Device Airway Balloon Catheter and Accessories (Inspira Air) (K090660)	Subject Device RELIEVA TRACT™ Balloon Dilation System
Indications for Use	An ear, nose, and throat manual surgical instrument is one of a variety of devices intended for use in surgical procedures to examine or treat the bronchus, esophagus, trachea, larynx, pharynx, nasal and paranasal sinus, or ear. This generic type of device includes the esophageal dilator; tracheal bistour (a long, narrow surgical knife); tracheal dilator; tracheal hook; laryngeal injection set; laryngeal knife; laryngeal saw; laryngeal trocar; laryngectomy tube; adenoid curette; adenotome; metal tongue depressor; mouth gag; oral screw; salpingeal curette; tonsillectome; tonsil guillotine; tonsil screw; tonsil snare; tonsil suction tube; tonsil suturing hook; antom reforator; ethmoid curette; frontal sinus-rasp; nasal curette; nasal rasp; nasal rongeur; nasal saw; nasal scissors; nasal snare; sinus irrigator; sinus trephine; ear curette; ear excavator; ear rasp; ear scissor, ear snare; ear spoon; ear suction tube; malleous ripper; mastoid gauge; microsurgical ear chisel; myringotomy tube inserter; ossici holding clamp; sacculotomy tack inserter; vein press; wire ear loop; microrule; mirror; mobilizer; ear, nose, and throat punch; ear, nose and throat knife; and ear, nose, and throat trocar.	The RELIEVA ULTIRRA® Sinus Balloon Catheter is an instrument intended to dilate sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures. It is also intended to irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic 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. It is also intended to irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.	The Airway Balloon Catheter is an instrument intended to dilate strictures of the airway tree.	The RELIEVA TRACT™ Balloon Dilation System is an instrument intended to provide increased intranasal space to facilitate access for endonasal and transnasal procedures and/or temporarily address nasal obstruction by displacing the inferior turbinate and lower nasal septum. The RELIEVA TRACT™ Balloon Dilation System is intended for use in ages 17 years or older.

Attribute	Predicate Device ENT Manual Surgical Instrument (21 CFR 874.4420)	Reference Device RELIEVA Solo Elite™ Sinus Guide Catheter (Ultirra) (K111254)	Reference Device Airway Balloon Catheter and Accessories (Inspira Air) (K090660)	Subject Device RELIEVA TRACT™ Balloon Dilation System
Intended Use	An ear, nose, and throat manual surgical instrument is one of a variety of devices intended for use in surgical procedures to examine or treat the bronchus, esophagus, trachea, larynx, pharynx, nasal and paranasal sinus, or ear. This generic type of device includes the esophageal dilator; tracheal bistour (a long, narrow surgical knife); tracheal dilator; tracheal hook; laryngeal injection set; laryngeal knife; laryngeal saw; laryngeal trocar; laryngectomy tube; adenoid curette; adenotome; metal tongue depressor; mouth gag; oral screw; salpingeal curette; tonsillectome; tonsil guillotine; tonsil screw; tonsil snare; tonsil suction tube; tonsil suturing hook; antom reforator; ethmoid curette; frontal sinus-rasp; nasal curette; nasal rasp; nasal rongeur; nasal saw; nasal scissors; nasal snare; sinus irrigator; sinus trephine; ear curette; ear excavator; ear rasp; ear scissor, ear snare; ear spoon; ear suction tube; malleous ripper; mastoid gauge; microsurgical ear chisel; myringotomy tube inserter; ossici holding clamp; sacculotomy tack inserter; vein press; wire ear loop; microrule; mirror; mobilizer; ear, nose, and throat punch; ear, nose and throat knife; and ear, nose, and throat trocar.	The RELIEVA ULTIRRA® Sinus Balloon Catheter is intended to dilate nasal anatomy, such as sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures.	The Airway Balloon Catheter is an instrument intended to dilate strictures of the airway tree.	The RELIEVA TRACT™ Balloon Dilation System is an instrument intended to provide increased intranasal space to facilitate access for endonasal and transnasal procedures and/or temporarily address nasal obstruction.

Attribute	Predicate Device ENT Manual Surgical Instrument (21 CFR 874.4420)	Reference Device RELIEVA Solo Elite™ Sinus Guide Catheter (Ultirra) (K111254)	Reference Device Airway Balloon Catheter and Accessories (Inspira Air) (K090660)	Subject Device RELIEVA TRACT™ Balloon Dilation System
Technological Characteristics	Intended for use in surgical procedures to examine or treat ENT spaces	Allows for dilation of sinus ostia with the added capability to irrigate	To dilate strictures of airway tree	Allows for dilation of nasal passage without irrigation
Single Patient Use	N/A	Yes	Yes	Yes
Direct Patient Contact	N/A	Yes	Yes	Yes
Balloon Diameter and Length	Not applicable	5mm x 16mm 6mm x16mm 7mm x 16mm 7mm x 24mm	5mm x 24mm 7mm x 24mm 8.5mm x 24mm 10mm x 40mm 12mm x 40mm 14mm x 40mm 16mm x 40mm	5mm x 24mm 7mm x 24mm 8.5mm x 24mm 10mm x 40mm 12mm x 40mm 14mm x 40mm 16mm x 40mm
Maximum Inflation Pressure	Not applicable	12 ATM	8-16 ATM	8-16 ATM
Flexible Shaft	Not applicable	Yes	Yes	Yes
Deflation Time	Not applicable	< 5 seconds	≤ 15 sec	≤ 15 sec
Catheter Length	Not applicable	250mm	450mm	450mm
Balloon Slide Mechanism	Not applicable	No	No	No
Irrigation Capability	Not applicable	Yes	No	No
Incorporated Suction	Not applicable	No	No	No
Accessory Devices Packed with Device	Varies	Stylet	Stylet	Stylet
Principles of Operation	ENT manual surgical instrument intended for use in surgical procedures to examine or treat ENT spaces.	Manually operated device. Balloon inflated with sterile saline or water to mechanically dilate sinus ostia.	Manually operated device. Balloon inflated with sterile saline or sterile water to mechanically to dilate strictures of the airway tree.	ENT manual surgical instrument. Balloon inflated with sterile saline or sterile water to mechanically dilate nasal passage.

[807.92(b) (1)] Determination of Substantial Equivalence	
Non-Clinical Performance Data:	The subject device, RELIEVA TRACT™ Balloon Dilation System, met all performance acceptance criteria. Packaging shelf life was evaluated in accordance with ASTM F1980-07, ASTM F88/F88M-09, and ASTM F2096-04 requirements and confirmed to meet a shelf life of 24 months. The sterilization process has been validated per 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". Biocompatibility testing was successfully completed to determine that the RELIEVA TRACT™ Balloon Dilation System is biocompatible per ISO 10993-1. Simulated use testing on cadavers was successfully conducted to verify that the RELIEVA TRACT™ Balloon Dilation System functions in accordance with its intended use and design specifications in a simulated clinical setting. The packaging and instructions for use were also successfully assessed by evaluators as part of the study.
[807.92(b) (2)] Determination of Substantial Equivalence	
Clinical Performance Data	Clinical data was not necessary for the RELIEVA TRACT™ Balloon Dilation System. The performance data demonstrated that the device performs as intended.
[807.92(b) (3)] Conclusion	
Conclusion from Non-Clinical and Clinical Tests	Based on the information provided in this premarket notification, Acclarent concludes that the RELIEVA TRACT™ Balloon Dilation System is as safe and as effective as and substantially equivalent to the predicate device.