K052198

510(k) Summary

AUG 3 1 2005

General Information

Classification:	Class I
Classification Name:	Ear, Nose & Throat Manual Surgical Instrument
Regulation Code:	21 CFR 874.4420
Product Code:	LRC
Trade Name:	*Relieva* Sinus Balloon Inflation Device
Submitter:	Acclarent, Inc. 1525-B O'Brien Drive Menlo Park, CA 94025
Contact:	Su-Mien Chong VP, Clinical, Regulatory and Quality
Date Revised:	25 August 2005

Intended Use

The *Relieva Sinus Balloon Inflation Device* is recommended for use to inflate the balloon, monitor the pressure within the balloon and deflate the balloon while performing balloon dilation procedures of the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures.

Device Description

The *Relieva Sinus Balloon Inflation Device* is a disposable inflation device with a manometer that measures pressures ranging from vacuum to gauge capacity.

Materials

All materials used in the manufacture of the *Relieva Sinus Balloon Inflation Device* are suitable for their intended use and have been used in numerous previously cleared products.

Testing

Products were tested to ensure conformance to product specification. Testing included:

- Pressure Accuracy
- Pressure Decay
- Predicate Comparison
- Pressure Integrity

Summary of Substantial Equivalence

The *Relieva Sinus Balloon Inflation Device* is substantially equivalent to marketed predicate devices with respect to intended use and technological characteristics.

Comparison Chart of Relieva Sinus Balloon Inflation Device and Predicate Devices

	Relieva Sinus Inflation Device	**Relieva Sinus Balloon Catheter**	**Circular Cutting Punch**	**Antrum Curette**
Manufacturer	Acclarent	ExploraMed NC1	Karl Storz Endoscopy America	Karl Storz Endoscopy America
510(k) Number	K052198	K043527	Pre-Amendments	Pre-Amendments
CFR Section	874.4420	874.4420	874.4420	874.4420
Device Classification	I	I	I	I
Product Code	LRC	LRC	LRC	LRC
Intended Use	Inflation & deflation of dilation balloon	Dilation of tissue	Dilation of tissue	Dilation of tissue
Working Diameter	8mm	3mm, 5mm, 7mm	4.5mm	5mm
Working Length	20 cm	30cm	18cm	19cm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2005

Acclarent, Inc.
c/o Su-Mien Chong
VP Cinical, Regulatory and Quality
1525-B O'Brien Drive
Menlo Park, CA 94025

Re: K052198
Trade/Device Name: Relieva Sinus Balloon Inflation Device
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, nose, and throat manual surgical instrument
Regulatory Class: Class I
Product Code: LRC
Dated: August 11, 2005
Received: August 12, 2005

Dear Ms. Chong

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052198

Device Name: *Relieva Sinus Balloon Inflation Device*

Indications for Use: The Relieva Sinus Balloon Inflation Device is recommended for use to inflate the balloon, monitor the pressure within the balloon and deflate the balloon while performing balloon dilation procedures of the sinus ostia and spaces within the paranasal sinus cavities for diagnostic and therapeutic procedures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K052198