MAY 22 2009

510(k) Summary of Safety and Effectiveness

BaroSense Endogastric Tube

BAROSENSE INC

General Information

Criteria	*Information*
Trade Name	BaroSense Endogastric Tube (*Note*: a trademark name is still being finalized and may be added to that listed above)
Product Name	Endogastric Tube (EGT)
Catalog/Model Number	Model # F0034
Common Name	Overtube
Classification	21 CFR 876.1500- Endoscope and Accessories; Class II; Product code: KOG
510(k) Owner	BaroSense, Inc. 3698-C Haven Ave. Redwood City CA 94063
Contact Person	Daniel J. Balbierz, Chief Operating Officer BaroSense, Inc. dbalbierz@barosense.com 650-362-6000 (phone) 650-362-0700 (fax)

Summary of Substantial Equivalence

The BaroSense Inc., Endogastric Tube does not raise any new safety or effectiveness issues and is substantially equivalent to legally marketed overtubes that are in commercial distribution, and has been determined to be substantially equivalent to devices in commercial distribution, prior to May 28, 1976.

Date: March 23, 2009

Substantially Equivalent Devices

Manufacturer	*Substantially equivalent device*	*510(k)*
US Endoscopy Mentor, OH	Guardus™ Disposable Overtube	K040836
NDO Surgical Mansfield, MA	Overtube	K002018
CR Bard, Inc. Billerica, MA	Endoscopic Overtube	K973500

Device Description

The BaroSense EGT is a single use, disposable, overtube used in hospitals or surgery centers to provide a channel for the delivery and removal of endoscopic devices from the mouth to the stomach. It is intended for use when multiple endoscopic intubations, or endoscopic instrument/tool exchanges, are anticipated.

The EGT is supplied non-sterile and is provided with a removable, flexible introducer with a tapered tip that assists in introduction of the EGT through the mouth and esophagus.

Indications for Use

The BaroSense EGT is indicated for use with an endoscope where multiple endoscopic intubations are anticipated.

Bench Testing

All patient contacting components of the EGT are composed of materials of known biocompatibility tested to the requirements of ISO 10993. The safety and effectiveness of the device was further established through a series of bench tests. All testing yielded acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

Mr. Daniel J. Balbierz
President and CEO
BaroSense, Inc.
3698-C Haven Avenue
REDWOOD CITY CA 94063

Re: K082589
Trade/Device Name: BaroSense Endogastric Tube (EGT), model F0034
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: March 30, 2009
Received: April 1, 2009

Dear Mr. Balbierz:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~K0802589~~ K082589

Device Name: Endogastric Tube (EGT)

Indications for Use: The BaroSense Endogastric Tube is indicated for use with an endoscope where multiple endoscopic intubations are anticipated.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082589