K120126

510(k) Summary

SEP 10 2012

BaroSense Endogastric Tube (EGT)

BAROSENSE INC.

General Information

Criteria	*Information*
Trade Name	BaroSense Endogastric Tube and Introducer Bougie
Product Name	Endogastric Tube (EGT) and Introducer Bougie
Catalog/Model Number	Model Number: BET-01 (overtube) BIB-01 (bougie)
Common Name	Overtube
Classification	21 CFR 876.1500- Endoscope and Accessories; Class II; Product code: FED
510(k) Owner	BaroSense, Inc. 250 Chesapeake Drive Redwood City CA 94063
Registration Number	3008849950
Contact Person	Sheila Stevens, PhD Director Clinical and Regulatory Affairs BaroSense, Inc. sstevens@barosense.com 650-362-6016 (phone) 650-362-0070 (fax)

Summary of Substantial Equivalence

The BaroSense, Inc., Endogastric Tube (EGT) and Introducer Bougie (Model BET-01 and BIB-01) are substantially equivalent to the BaroSense Endogastric Tube (EGT) Model F0034.

Date: March 13, 2012

Predicate Devices

Manufacturer	*Predicate device*	*510(k)*
BaroSense, Inc. Redwood City, CA	Endogastric Tube (EGT)	K082589

Device Description

The EGT is a reusable 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. A flexible Introducer Bougie has a tapered tip to assist in introduction of the EGT through the mouth and esophagus. The bougie has an internal lumen to accommodate a 5 mm endoscope.

The EGT and Introducer Bougie are supplied non-sterile.

The predicate device has identical technological characteristics. However, the predicate EGT is provided as a single-patient-use, disposable unit, with an internal bougie introducer included in the package. The modified device is provided as a reusable overtube and single-use bougie. The predicate device working tube is a PVC tube with an embedded stainless steel reinforcement coil, whereas the modified device is a Tecoflex tube with an embedded stainless steel reinforcement coil. The proximal handle of the modified device has an added feature to allow the endogastric tube to grip and seal to Introducer Bougie or other endoscopic devices. This gripping action prevents relative motion between the overtube and the other devices, e.g., the Introducer Bougie.

Indications for Use

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

Bench/Animal Testing

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sheila Stevens, Ph.D.
Director, Clinical and Regulatory Affairs
BaroSense, Inc.
250 Chesapeake Drive
REDWOOD CITY CA 94063

SEP 10 2012

Re: K120126
Trade/Device Name: BaroSense Endogastric Tube (EGT)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: August 13, 2012
Received: August 14, 2012

Dear Dr. Stevens:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K120126

Device Name: BaroSense Endogastric Tube (EGT)

Indications for Use: The BaroSense Endogastric Tube (EGT) 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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120126

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