JUN - 3 2011

III. 510(k) Summary

BaroSense ACE™ Stapler and Cartridge

BAROSENSE INC.

General Information

Criteria	*Information*
Trade Name	ACE™ Stapler (*Note*: the trademark name is still being finalized and may change from that listed above)
Product Name	ACE Stapler and Cartridge
Catalog/Model Number	F0084 ACE Stapler Reusable Handle F0085 ACE Stapler Head F0087 ACE Stapler Cartridge
Common Name	surgical stapler and cartridge
Classification	21 CFR 876.1500- Endoscope and Accessories; Class II; Product code: OCW
510(k) Owner	BaroSense, Inc. 250 Chesapeake Drive Redwood City CA 94063
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., ACE Stapler and Cartridge (component models F0084, F0085 and F0086) are substantially equivalent to the BaroSense ACE Stapler and Cartridge (component models F0031 and F0007).

Date: March 22, 2011

Predicate Devices

Manufacturer	*Predicate device*	*510(k)*
BaroSense, Inc. Redwood City, CA	ACE Stapler, model F0031 ACE Stapler Cartridge, model F0007	K082044

Device Description

The ACE™ Stapler is a surgical stapler used in hospitals or surgery centers for staple closure on the wall of the stomach or gastrointestinal tract.

The single-patient-use, disposable stapler head is supplied non-sterile and is fitted with a sterile, single-use staple cartridge. The stapler head is attached to a reusable, flexible stapler handle that controls the position and articulation of the stapler head. In use, the stapler is introduced into the patient through the mouth. A flexible endoscope passes through the stapler for gastric tissue visualization. The stapler works in conjunction with a vacuum pump to create a plication [tissue fold] in the GI tract, which is then compressed. The stapler then places a double, circular row of titanium staples. A non-absorbable ring helps reinforce the staple placement in the tissue. The tissue compression and stapling functions are controlled by commercially available inflation syringes.

The stapler may be introduced over a guidewire. If multiple plications are required, an endogastric overtube may be used to protect the esophageal tissues during repeated insertions of the device. The guidewire, overtube, flexible endoscope, vacuum pump and inflation syringes used with the stapler are all commercially available medical devices, not the subject of this 510(k), and are not supplied with the stapler.

The predicate device has identical technological characteristics. However. the predicate stapler device is provided as a single-patient-use, non-sterile, disposable unit. The predicate device is introduced through an overtube, as it does not include a membrane designed for guidewire introduction.

Indications for Use

The BaroSense ACE Stapler is indicated for endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract.

Bench/Animal Testing

All patient contacting components of the ACE Stapler 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 and animal tests. All testing yielded acceptable results.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11137-1:2006 Sterilization of Health Care Products - Radiation- Part 1:

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-297		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table. [4]	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☑ Special ☐ Abbreviated

STANDARD TITLE[1]

ISO 11137-2:2006 Sterilization of Health Care Products - Radiation- Part 2:

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA[2]?	☑	☐
FDA Recognition number[3] # 14-225		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report[4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
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[2] Authority [21 U.S.C. 360d]. www.fda.gov/cdrh/stdsprog.html

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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE [1]

10993-1:2009 Biological evaluation of medical devices -- Part 1:Evaluation and testing (Biocompatibility)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 2-156		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
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[2] Authority (21 U.S.C. 360d), www.fda.gov/cdrh/stdsprog.html

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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

JUN - 3 2011

Re: K110829
Trade/Device Name: ACE Stapler and Cartridge, Models F0084, -85 and -86
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated: April 28, 2011
Received: May 6, 2011

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Statement of Indications for Use

510(k) Number (if known): K110829

Device Name: ACE™ Stapler and Cartridge

Indications for Use: The BaroSense ACE Stapler and Cartridge are indicated for endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract.

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 K110829

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