pg 1 of 2

2. 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Date Prepared: February 6, 2012

510(k) number: K120440

Applicant Information:

Sontina Medical, LLC
111 Sutro Heights Ave
San Francisco, CA 94121

Contact Person: Robert Peliks
Phone Number: (415) 873 – 3831
Fax Number: (415) 668 – 4884

Device Information:

Classification:	Class II
Trade Name:	Presto Breast Biopsy Device
Common Name:	Biopsy Instrument
Classification Name:	Biopsy Instrument (21 CFR 876.1075)
Product Code:	KNW

Predicate Device Information:

The subject device is substantially equivalent in intended use and/or method of operation to the devices listed in **Table 2.1**.

Table 2.1 Predicate Device Information

Device Name	Manufacturer	510(k) #
Rubicor Magic Breast Biopsy Device	Encapsule Medical (San Francisco, CA)	K071048
Bard Monopty	Bard Biopsy Systems (Tempe, AZ)	K922939

Device Description:

The Presto Breast Biopsy Device is a sterile, single-use percutaneous biopsy device. The working end of the device includes a stainless steel coring cannula with a razor edge and a stationary coil located within the coring cannula. The handle of the device contains an actuation button, a sample collection chamber, a drive mechanism for rotating the coring cannula and a DC power jack for a 12V input. A reusable, medical grade AC/DC power supply provides 12V to the disposable device. Depressing the button on the handle rotates the coring cannula – allowing the operator to core and transport tissue samples to the collection chamber. The device may be used with a coaxial introducer.

Intended Use:
The Presto Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses.

The Presto Breast Biopsy Device is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Device Comparison:
The Presto Breast Biopsy device shares many similarities with one or all of the predicate devices, including:

- Similar indications for use and anatomical target site;
- Similar features, including:
  - Single, Insertion –Multiple Sample functionality
  - One-button user-interface
  - Compatibility with coaxial introducer
  - Echogenic working-end;
- Similar materials – the working end of all devices is predominantly stainless steel; and
- Similar device functionality – a reusable, medical grade AC-DC power supply powers a DC motor which spins a forward advancing, spinning cannula to core & severe the targeted specimen.

Testing Summary:
The Presto Breast Biopsy Device was evaluated in the following non-clinical studies: in-vitro device performance, electrical & product safety (IEC 60601-1), tensile strength & fatigue, biocompatibility, predicate device comparison and simulated use testing.

Results of the testing demonstrate that the materials, manufacturing process and design of the Presto Breast Biopsy Device meet the established specifications necessary for consistent performance during its intended use

Conclusion:
Based on the intended use, product, and performance information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed and unmodified predicate devices.

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

MAY 17 2012

Sontina Medical, LLC
% Mr. Robert Peliks
111 Sutro Heights Avenue
San Francisco, California 94121

Re: K120440
Trade/Device Name: Presto Breast Biopsy Device
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: April 24, 2012
Received: April 26, 2012

Dear Mr. Peliks:

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,

for Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use Statement

510(k) Number (if known): N/A

Device Name: Presto Breast Biopsy Device

Indications for Use:

The Presto Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses.

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

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

Concurrence of CDRH, Office of Device Evaluation

Neil R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120440