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SECTION 012 – SUMMARY OF SAFETY AND EFFECTIVENESS

1 General Information

MAY 18 2009

Submitter's Name and Address:	Transoma Medical, Inc. 119 14th Street NW Suite 200 St. Paul, MN 55112 Phone: 651-414-5521 Fax: 651-481-7415
Contact Person:	Lisa Stone Phone: 651-414-5521 Fax: 651-481-7415 Email: lstone@transomamedical.com
Date of Summary:	April 23, 2009
Proprietary Name of Device:	Sleuth AT Implantable Cardiac Monitoring System
Common/Usual Name:	Implantable ECG Monitoring System
Classification Name:	Cardiac Implantable Event Recorder Product Code – MXC 21 CFR Part 870.2800 Device Class II
Legally Marketed Device to Which Substantial Equivalence is Claimed:	Sleuth AT Implantable Cardiac Monitoring System (K083828)

2 Device Description

The Sleuth AT Implantable Cardiac System is an electrocardiogram (ECG) monitoring system that includes an implantable component and that provides continuous ECG monitoring and episodic or segmented ECG recording. The Sleuth AT Implantable Cardiac System comprises three interrelated components: Implantable Loop Recorder (ILR), Personnel Diagnostic Manager (PDM) and Base Station.

The PDM software was updated from Version 4.2 to Version 4.3. The Version 4.3 software incorporates a Service Menu in the PDM and minor software bug fixes. The Service Menu includes time zone set-up, data review option and transfer log. No other changes to the system were made.

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3 Intended Use

The Transoma Medical Sleuth AT Implantable Cardiac Monitoring System is an implantable, patient- and automatically-activated monitoring system that records subcutaneous ECG and is indicated for:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia

4 Summary of Technological Characteristics

The Sleuth AT System incorporates substantially equivalent technology, comparable features, labeling, and intended use, and is similar to the predicate device currently available on the market.

5 Non-clinical Test Summary

The substantial equivalence of Sleuth AT System has been demonstrated via software design verification and validation testing.

6 Conclusion

Based on the information provided above, the Sleuth AT System incorporating the Service Menu is substantially equivalent to the predicate Sleuth AT System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2009

Transoma Medical, Inc.
c/o Ms. Lisa Stone
Regulatory Affairs Manager
119 14th Street NW
Suite 200
St. Paul, MN 55112

Re: K091206
Trade/Device Name: Sleuth AT Implantable Cardiac Monitoring System
Regulation Number: 21 CFR 870.2800
Regulation Name: Cardiac Implantable Event Recorder
Regulatory Class: Class II (two)
Product Codes: MXC
Dated: April 23, 2009
Received: April 24, 2009

Dear Ms. Stone:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091206

SECTION 008 – LABELING AND INTENDED USE

Indications for Use

510(k) Number (if known): _____

Device Name: Sleuth AT Implantable Cardiac Monitoring System

Indications for Use:

The Sleuth AT system is an implantable, patient- and automatically-activated monitoring system that records subcutaneous ECG and is indicated for:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091206