SECTION 012 – SUMMARY OF SAFETY AND EFFECTIVENESS

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1 General Information

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Submitter's Name and Address:	Transoma Medical, Inc. 119 14th Street NW 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:	February 3, 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 Implantable ECG System K063035 and K073147

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 Sleuth AT System incorporates modified brady, asystole, and tachy detection algorithms; additional trending capabilities; EMG detection/rejection; and program pending mode when compared to the original Sleuth System. There are no changes to the Indications for Use and only minor mechanical updates to the ILR and PDM.

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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 bench testing, including:

- Mechanical
- Electrical Safety, Immunity and Compatibility
- Heart Rate Detection
- Event Detection
- ECG Measurement Accuracy
- General Electrical Operation
- ECG Input Tolerance
- Communication Interface
- RF Communication Performance
- Battery Life
- ASIC Accelerated Life
- ASIC Battery Voltage Measurement
- System Function and Environment
- Evaluation of New Algorithm

6 Clinical Study Summary

A clinical study (PULSE study) was conducted on the original version of the Sleuth system (Model 2010) at four major medical centers in Panama. The results of that study still support the new device Sleuth AT, due to the similarities between the two devices and verifications presented in the 510(k) Notification. The primary objectives of the PULSE study were to evaluate the diagnostic viability of the ECG signals and the performance of

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the system. Twenty-eight (28) patients were enrolled in the study. The patients had unexplained syncope/ pre-syncope or were at risk of arrhythmias. The results supported adequate viability of the ECG signals for the diagnosis of various arrhythmias. In the auto-triggers from the population studied, it was found that the true and false positive rates were 0.23% and 99.77%, respectively.

Based on the similarity of the two devices, the new Sleuth AT's arrhythmia detector was verified using standard ECG databases, and ECGs collected in the above study of the predicate Sleuth system. The sensitivity and positive predictive value of R-wave detection was 98.6% and 99.5% (MIT-BIH data base), which is similar or better than the predicate Sleuth system. Furthermore, when the collected clinical data was applied to the Sleuth AT detector, the percentage of auto-triggered events that were false positives was found to be 95.96%, while the fraction of true positive autotriggers was 4.04%.

7 Conclusion

Based on the information provided above, the Sleuth AT System is substantially equivalent to the Sleuth System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2009

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

Re: K083828
Trade/Device Name: Sleuth AT Implantable Cardiac Monitoring System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MXC
Dated: January 29, 2009
Received: January 30, 2009

Dear Ms. Stone:

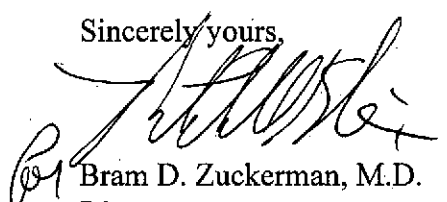
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (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

Indications for Use

510(k) Number (if known): K083828

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)

for B Zuckerman

(Division Sign-Off) 2/11/09

Division of Cardiovascular Devices

510(k) Number K083828