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CONFIDANT

JAN - 9 2009

510(K) SUMMARY

In accordance with 21 CFR 807.92, the following information constitutes Confidant's summary for the Confidant 2.6 System.

SUBMITTER'S NAME:	Confidant International, LLC
ADDRESS:	2530 Meridian Parkway, Suite 300
CONTACT PERSON:	Daniel R. Plonski
CONTACT PERSON TITLE:	Director of Product Management
TELEPHONE NUMBER:	(919) 806-4323
FAX NUMBER:	(919) 806-4802
DATE OF SUBMISSION:	November 7, 2008

1 Identification of device

Proprietary Name: Confidant 2.6
Common Name: Physiological Transmitter and Receiver
Classification Status: Class II per regulations 870.2910
Product Codes: DRG

2 Equivalent devices

Confidant Inc. believes that Confidant 2.6 is substantially equivalent to the following legally marketed device:

Confidant 2.5
K072698
Confidant International, LLC

3 Description of the device

Confidant 2.6 is an accessory device that collects data from a range of supported home-monitoring devices. The data is collected from the supported devices and sent to a central database server, using standard communication technologies. Upon receipt of newly submitted patient data, the Confidant Server software will generate and send one or more feedback messages directly to the patient, via cell-phone or personal computer. The feedback messages are selected by the system based on the patient's currently submitted and recent historic data. Confidant 2.6 currently supports several models of glucose meters, a non-invasive blood pressure cuffs and a weight scale.

2530 Meridian Parkway, Ste 300 Durham, NC 27713
(W) 919.806.4620 (F) 919.806.4802
confidantinc.com

4 *Intended use*

Confidant 2.6 is intended for personal use by out-of-hospital patients as a means to retrospectively collect and record physiologic measurements from home monitoring devices (including blood glucose meters, blood pressure cuffs and weight scales). The data is transmitted to a database server where customized messages are generated by the system and returned to the patient. The returned messages contain objective observations and motivational information intended to help the patient better understand and manage their health.

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Confidant 2.6 does not provide diagnosis of any disease or medical condition.

Confidant 2.6 is not intended to provide automated treatment decisions, or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Confidant 2.6 is not intended for emergency calls or for transmission or indication of any real-time alarms or time-critical data. This device is not intended as a substitute for direct medical supervision or emergency intervention.

Confidant 2.6 is intended for over-the-counter use.

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5 *Technological characteristics, comparison to predicate device.*

Confidant 2.6 utilizes the same technology as the predicate device (Confidant 2.5, K072698) including:

- The same types of supported monitoring devices
- The same operational features
- The same fundamental technology

6 *Discussion of functional and safety testing.*

Testing of Confidant 2.6 included functional performance testing of the new PC Interface software component; and low-level, device compatibility verification for the OMNIS glucose meter. The test results demonstrate that Confidant 2.6 is in compliance with the applied standards and that it performed within its specifications and functional requirements.

7 *Conclusion*

Based on the comparison of intended use, supported monitoring devices, operational features and technology and the results of functional performance, and device compatibility testing, it is our conclusion that Confidant 2.6 is as safe, as effective and performs as well as the legally marketed predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2009

Confidant International, LLC
c/o Mr. Daniel R. Plonski
Director of Product Management
2530 Meridian Parkway, Suite 300
Durham, North Carolina 27713

Re: K083331
Trade/Device Name: Confidant 2.6 System
Regulation Number: 21 CFR 870.2910
Regulation Name: Physiological Transmitter and Receiver
Regulatory Class: Class II
Product Codes: DRG, NBW
Dated: December 29, 2008
Received: December 30, 2008

Dear Mr. Plonski:

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

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 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,

for 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): K083331

Device Name: Confidant 2.6

Indications For Use: Confidant 2.6 is intended for personal use by out-of-hospital patients as a means to retrospectively collect and record physiologic measurements from home monitoring devices (including blood glucose meters, blood pressure cuffs and weight scales). The data is transmitted to a database server where customized messages are generated by the system and returned to the patient. The returned messages contain objective observations and motivational information intended to help the patient better understand and manage their health.

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Confidant 2.6 is intended for over-the-counter use.

Prescription Use _____ **And/Or** **Over the Counter Use** ___X___.
(21 CFR Part 801 Subpart D) **(21 CFR Part 801 Subpart C)**

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

Concurrence of CDRH, Office Device Evaluation (ODE)

(Division Sign-Off) 1/8/09
Division of Cardiovascular Devices

510(k) Number K083331