K 122483

Section 1.2 510(k) Summary

JAN 0 3 2013

Submitter Information

Company: Asante Solutions
352 East Java Drive
Sunnyvale, CA 94089
(408) 716-5600

Robin Bush
Regulatory Project Manager

Summary Date: August 10, 2012

Name and Classification

Common Name:	Insulin Infusion Pump
Proprietary Name:	Pearl™ Diabetes Management System
Classification Name:	Pump, Infusion, Insulin
Product Code:	LZG
Regulation Number:	880.5725
Class:	II

Predicate Devices

The Pearl Diabetes Management System has the same intended use as a number of commercially available medical devices, operates within an established range of insulin delivery, and uses existing established technology also known as Continuous Subcutaneous Insulin Infusion (CSII).

a) Pearl Diabetes Management System (#K100567, Asante Solutions)

Reference Devices

a) Animas IR1200 (#K032257, Animas Corporation)

b) D-TRONplus (K043000, Disetronic)

Intended Use

The Pearl Diabetes Management System is intended for continuous, subcutaneous delivery of insulin at programmable basal and bolus rates for the management of diabetes mellitus in adult patients requiring insulin.

Description of Device

The Pearl Diabetes Management System is a continuous, programmable insulin delivery system. It consists of a controller, a single use pump body and an infusion set adapter. The controller unit has a user interface to program delivery parameters for basal and bolus insulin delivery. It attaches to the pump body. The pump body provides the drive mechanism and battery power and holds the pre-filled insulin cartridges. The infusion set adapter is the conduit from the insulin cartridge to the final delivery tubing.

Summary of Technological Characteristics

The system uses existing established and unchanged technology and materials, relative to the previously cleared device. The system employs the same drive mechanism as that of the cleared Pearl System (#K100567) to apply controlled and accurate force to move the plunger in the insulin cartridge. The microprocessor based controller is unchanged.

Performance Testing

The system has been verified for performance and functionality to provide assurance that the device modifications have been designed and tested to assure conformance to the requirements for its intended use.

The following are the major tests that were performed on the Pearl Pump System to support the modifications:

- accuracy
- altitude and altitude shock
- free fall
- liquid ingress
- positive and negative elevation
- system occlusion
- software validation

Conclusion

Performance testing on the modified device demonstrated that the Pearl Diabetes Management System performs reliably and delivers insulin as intended through the Asante Infusion Sets, and is safe for its intended use. Design verification testing confirmed that no new questions of safety or effectiveness were identified during device testing of the modified device.

Based upon the successful safety and performance tests and the similarities to predicate device, the modified Pearl Diabetes Management System is substantially equivalent to the predicate Pearl System in design, features, performance, fundamental scientific technology, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 3, 2013

Mr. Robin Bush
Project Manager, Regulatory Affairs
Asante Solutions, Incorporated
352 East Java Drive
SUNNYVALE CA 94089

Re: K122483
Trade/Device Name: Pearl™ Diabetes Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: December 18, 2012
Received: December 18, 2012

Dear Mr. Bush:

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.

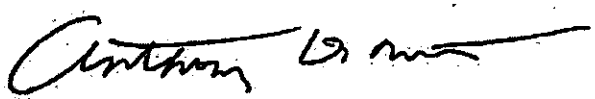
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1.1 Indications for Use

510(k) Number: K122483

Device Name: Pearl™ Diabetes Management System

Indications for Use: The Pearl Diabetes Management System is indicated for the continuous subcutaneous delivery of insulin at programmable basal and bolus rates for the management of diabetes mellitus in adult patients requiring insulin.

Prescription Use √ and/or Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122483

Keith G. Marin

Digitally signed by Keith G. Marin
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Keith G. Marin, 0.9.2342.19200300.100.1.1=00112 50397
Date: 2013.01.03 16:07:51 -05'00'