510(k) Summary

Submitter Information

Company:	Asante Solutions 1012 Stewart Drive Sunnyvale. CA 94085 (408) 716-5600
Contact Person:	Naghmeh Nouri Vice President of Quality Assurance and Regulatory Affairs
Summary Date:	May 09, 2011

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 technology that is substantially equivalent to the identified predicates.

a) Disetronic D-TRON and D-TRONplus (K994186, K043000).

b) Animas IR1200 (K032257).

Intended Use

The intended use of the Pearl Diabetes Management System is 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, a single use adapter and associated accessories. The controller unit has a user interface to program delivery parameters for basal and bolus insulin delivery and attaches to the pump body. The pump body provides the drive mechanism and battery power for pre-filled insulin cartridges. The adapter connects the insulin cartridge to the infusion set and contains the occlusion sensor.

Summary of Technological Characteristics

The system uses existing established technology, materials, and construction techniques. The system employs a ratchet drive mechanism to apply controlled and accurate force to the plunger movement of the insulin cartridge. The dual microprocessor based controller allows safety monitoring for basal and bolus insulin delivery. Occlusion is detected by monitoring an optical based pressure sensor located in the adapter.

Performance Testing

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

The following tests were performed on the Pearl Pump System:

- accuracy
- free fall drop
- altitude, altitude shock, and positive and negative elevation
- environmental testing
- occlusion sensing
- power management
- shipping and packaging testing
- single fault condition testing
- Mechanical and electrical safety testing was performed in accordance to EN 60601-1 and the specific requirements of IEC 60601-2-24
- Electromagnetic compatibility testing was performed in accordance to EN 60601-1-2.

User EvaluationTesting

User assessment evaluations and human factors validation studies were conducted under simulated use conditions to verify product understanding, programming modalities and pump operation. The users were provided a user manual and were trained by professional diabetic educators. Usability testing demonstrated the Pearl Diabetes Management System performs as designed and intended, and is safe and effective for its intended use.

Biocompatibility Testing

The biocompatibility of the flow path of the Pearl Pump device was assessed in accordance with ISO 10993-1:2009 – *Biological evaluation of medical devices, Part 1 – Evaluation and tests within a risk management process.*

The biocompatibility tests listed below were conducted in accordance with the provisions of the FDA GLP regulations 21 CFR Part 58.

- Cytotoxicity – MEM Elution Test using L-929 Mouse Fibroblast cells (ISO)
- Sensitization – Local Lymph Node Assay (LLNA)
- Sensitization – ISO Guinea Pig Maximization Sensitization Test
- Irritation – Intracutaneous Reactivity (Irritation) Test
- Systemic Toxicity – USP/ISO Systemic Injection Test
- Systemic Toxicity – USP/ISO Systemic Injection
- Genotoxicity – Salmonella Typhimurium Reverse Mutation Assay (Ames Test)
- Genotoxicity – In Vitro Mouse Lymphoma Assay
- Implantation – ISO Intramuscular Implant Test 7-Day Duration in Rabbits
- Bacterial Endotoxin (LAL) – USP Test

The biocompatibility test results confirmed that the flow path materials are non-cytotoxic, non-sensitizing, non-irritating, not systemically toxic, and non-genotoxic when evaluated under the respective test conditions.

The flow path material has also been tested for insulin compatibility and was confirmed to be compatible with Humalog®.

Conclusion

Based upon the successful safety and performance tests and the similarities to predicate devices, the Pearl Diabetes Management System is substantially equivalent to the predicate devices in design, features, performance, materials, packaging, fundamental scientific technology, and intended use.

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

Ms. Naghmeh Nouri
Vice President, Quality and Regulatory Affairs
M2 Group Holdings, Incorporated
1012 Stewart Drive
Sunnyvale, California 94085

MAY 10 2011

Re: K100567
Trade/Device Name: Pearl Diabetes Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: April 11, 2011
Received: April 12, 2011

Dear Ms. Nouri:

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

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

Enclosure

Indications for Use

510(k) Number: K100567

Device Name: Pearl™ Diabetes Management System

Indication for Use: 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 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 5/10/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100567