AUG 16 2005

K050971

510(K) SUMMARY

9.0 Summary of Safety and Effectiveness

9.1 Submitted By: Scott Huie
Vice President of Operations
Biovalve Technologies, Inc
Date Prepared: April 15, 2005

9.2 Trade/Proprietary Name: BioValve Insulin Delivery Systems (BIDS)

9.3 Common/Usual Name: Disposable Insulin Infusion Pump

9.4 Classification Name: Pump, Infusion, Insulin/Set, Administration, Intravascular

9.5 Classification: FDA has classified Infusion Pumps and Intravascular Catheters in Class II. Final Order was published in the Federal Register on October 21, 1980 after review by the General Hospital and Personal Use Devices Classification Panel.

Panel: 80 Procodes:	LZG	External Insulin Infusion Pump
	FPA	Intravascular Administration Set

9.6 Purpose of Submission
BioValve Technologies proposes to market a disposable pump for the basal and bolus delivery of insulin.

9.7 Substantial Equivalence
The BioValve Insulin Delivery Systems (BIDS) is substantially equivalent to the Insulet iXL Diabetes Management System (K031373) as well as other Insulin Infusion Pumps and Subcutaneous Insulin Infusion Sets.

9.8 Technological Characteristics
The technological characteristics for these devices differ from the predicate devices in as much as this device does not use electronic power or components nor is it software controlled.

9.9 Performance Data
The information provided supports that the performance of the pumps is equivalent to the predicate devices.

9.10 Conclusion
Biovalve, Inc. concludes based on the information presented that the modified product is substantially equivalent to the current product legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2005

Mr. Scott Huie
Vice President of Operations
BioValve Technologies, Incorporated
155 Flanders Rd.
Westborough, Massachusetts 01581

Re: K050971
Trade/Device Name: BioValve Insulin Delivery Systems (BIDS)
Regulation Number: 21 CFR 880.5725
Regulation Name: Insulin Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: June 30, 2005
Received: July 1, 2005

Dear Mr. Huie:

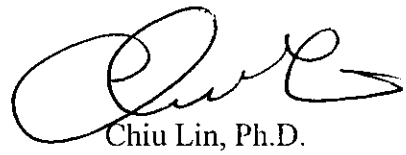
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
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 (if known): K050971

Device Name: BioValve Insulin Delivery Systems (BIDS)

Indications For Use:

The BioValve Insulin Delivery System (BIDS) is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons 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: K050971