510(k) Summary of Safety and Effectiveness

JAN 20 2010

510(k) Summary of Safety and Effectiveness
This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92(c).

1. Owner's Name, Address, Telephone Number, Contact Person

Name, Address, Telephone Number

Calibra Medical, Inc.
220 Saginaw Drive
Redwood City, CA 94063-4725

Contact Person

Richard J. Meader
Vice President Regulatory and Quality Affairs
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Date Prepared

January 20, 2010

2. Trade Name

Finesse Personal Insulin Delivery Patch

3. Common Name

Disposable Insulin Infusion Pump

4. Classification Name

Pump, infusion, insulin bolus

5. Classification

Code of Federal Regulations Number	880.5725
Classification Panel	General Hospital
Product Code	OPP (Primary) LZG (Secondary)
Regulatory Class	Class II
Review Category	Tier 2

6. Identification of the Predicate or Legally Marketed Device

Calibra Medical, Inc. believes that the System described in this Submission is substantially equivalent to a combination of the Eli Lilly and Company HumaPen Memoir (K053563) and the Biovalve Insulin Delivery System (K050971).

7. Device Description

The Finesse Insulin Delivery System is a sterile, nonpyrogenic, single-use, external, disposable, ambulatory, insulin, bolus dosing system through which clinician-prescribed medications are delivered subcutaneously. The Finesse Insulin Delivery System is composed of a positive volume displacement drug delivery device with infusion cannula and integrated Inserter, and drug delivery device filler. The device is adhered to the skin for up to 48 hours with a biocompatible adhesive.

The Finesse Insulin Delivery System has an integrated cannula and Inserter. The infusion cannula Inserter is used to place the cannula in the subcutaneous tissues. It contains an insertion needle located in the lumen of the infusion catheter cannula. A safety mechanism prevents premature actuation of the insertion needle mechanism to prevent injuries. Following cannula placement, the needle is retracted within the body of the Inserter to prevent sharps exposure. Once the needle is retracted, the Inserter automatically releases the Inserter from the drug delivery component.

The Finesse Insulin Delivery System materials are biocompatible plastics, elastomers, and stainless steel.

8. Intended Use

The Finesse Insulin Delivery System is intended for the subcutaneous, bolus delivery of insulin for the management of *diabetes mellitus* in persons requiring insulin.

9. Technological Characteristics

The Finesse Insulin Delivery System meets the description of a pump, infusion, insulin as established in product code OPP. The system is identical to other insulin delivery devices in that it uses a positive volume displacement type of manual piston to precisely deliver discrete doses of medication from the internal reservoir. The Finesse has no power source. It is non-electrically powered. The Finesse piston is actuated by the mechanical action of the user's fingers pressing on the buttons. The Finesse has a reservoir to hold the medicinal product (insulin). The Finesse has a single lumen catheter/cannula that delivers the drug to the subcutaneous tissues. The Finesse is used by a health care professional, a patient, or a patient care-giver to deliver the drug (i.e., drug delivery requires competent human interaction).

The Finesse is worn for up to 48 hours and has a flexible cannula placed in the subcutaneous tissues to deliver insulin. This is equivalent to the characteristics of the BioValve device

10. Non-Clinical Performance Data

Data establishing conformance to the following consensus standards and FDA guidance is maintained in the design history file and establishes the substantial equivalence with the predicate devices. The conclusions drawn from the data support the equivalence, safety, and effectiveness of the system.

Consensus Standards and FDA Guidance	
Number	**Title**
ANSI/AAMI/ISO 10993-1: 2003	Biological evaluation of medical devices -- Part 1: Evaluation and testing
USP30-NF25	Assays: 85 Bacterial Endotoxins Test, 121 Insulin Assays, 591 Zinc Determination, 621 Chromatography, 791 pH

Consensus Standards and FDA Guidance	
Number	**Title**
ANSI/AAMI HE74: 2001	Human factors design process for medical devices
IEC 62366 Edition 1.0 2007-10	Application of usability engineering to medical devices
ASTM D 4169 – 05:2005	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F 88 – 07a:2007	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F 1929 – 1998 (2004)	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F 1980 – 2007	Standard Guide for Accelerated Aging of Sterile Medical Device Packages
ANSI/IEC 60529: 2004	Degrees Of Protection Provided By Enclosures
ISO 7864:1993	Sterile Hypodermic Needles for single use
ISO 8537:1991, A1:2000	Sterile single-use syringes, with or without needle, for insulin
ISO 9626:1991, A1:2001	Sterile single-use intravascular catheters —Part 1 General requirements
ISO 10555-1-1995, A1-1999, A2-2004	Sterile single-use intravascular catheters —Part 1 General requirements
ISO 10555-5-1996, A1-1999, TC1: 2002	Sterile, single-use intravascular catheters —Part 5 Over-needle peripheral catheters
ISO 11608-1:2000	Pen-injectors for medical use — Part 1 Pen-injectors — Requirements and test methods
ANSI/AAMI ST67:2003	Sterilization of health care products—Requirements for products labeled "STERILE"
ANSI/AAMI/ISO 11137–1: 2006	*Sterilization of health care products*— Radiation— Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
ANSI/AAMI/ISO 11137-2:2006	Sterilization of health care products —Radiation —Part 2: Establishing the sterilization dose
ANSI/AAMI/ISO 11607-1: 2006	Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

Consensus Standards and FDA Guidance	
Number	**Title**
ANSI/AAMI/ISO 11607-2: 2006	Packaging for Terminally Sterilized Medical Devices Part 2: Validation Requirements for Forming, Sealing and Assembly Process
ISO 15223: 2000, A1: 2001, A2: 2004	Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied
ANSI/AAMI/IEC TR60878: 2003	Graphical symbols for electrical equipment in medical practice
FDA Guidance April 1993	Guidance on the Content of Premarket Notification 510(k) Submissions for Piston Syringes
FDA Guidance March 1995	Guidance On Premarket Notification 510(K) Submission For Short-Term And Long-Term Intravascular Catheters

11. Clinical Performance Data

No clinical performance data is required to validate the intended uses and user needs of the system. Design validation is completed by human factors simulated use testing.

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

Mr. Richard J. Meader
Vice President of Regulatory and Quality Affairs
Calibra Medical, Incorporated
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JAN 20 2010

Re: K093065
Trade/Device Name: Finesse Personal Insulin Delivery Patch
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: OPP, LZG
Dated: December 29, 2009
Received: December 30, 2009

Dear Mr. Meader:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. 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 (if known): Not known.

Device Name: Finesse Personal Insulin Delivery Patch

The Finesse Insulin Delivery System is intended for subcutaneous, bolus delivery of insulin 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 801 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: K093005