K111924

510(k) Summary of Safety and Effectiveness

APR 10 2012

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
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Contact Person

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Date Prepared

July 5, 2011

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 the Calibra Medical Finesse Insulin Delivery System cleared under 510(k)s K093065 and K100947.

7. Device Description

The Finesse Insulin Delivery System (IDS) is comprised of a sterile, nonpyrogenic, single-use, external, disposable, ambulatory, liquid medication, bolus dosing device (IDD); a single use, non-pyrogenic, sterile, syringe and needle (Fill Syringe);a reusable Inserter; and a Dose Count Card. The device is intended for subcutaneous delivery of clinician-prescribed medications, and is adhered to the skin for up to 72 hours with a biocompatible adhesive.

The Insulin Delivery Device (IDD) is a manual, user filled, positive displacement, bolus dosing pump. The Inserter is used to place the IDD on the skin and simultaneously implant the cannula into the subcutaneous tissues. The syringe and needle are for patient filling of the IDD with liquid medication prior to deployment on the body, and have a maximum capacity of 2ml. The Dose Count Card is utilized by the patient during the dosing session and provides for a written record of date, time and amount of Insulin delivery.

The Finesse IDS materials are biocompatible plastics, elastomers, and stainless steel.

8. Intended Use

The Finesse Insulin Delivery System is indicated for the subcutaneous, bolus delivery of physician prescribed insulins, in adult persons requiring such medications for the management of *diabetes mellitus*.

9. Technological Characteristics

The Finesse Insulin Delivery System meets the description of a pump, infusion, insulin bolus as established in product code 80-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 72 hours and has a flexible cannula placed in the subcutaneous tissues to deliver insulin. This is equivalent to the characteristics of the Calibra Medical Finesse Insulin Delivery System (product code 80-OPP) cleared under 510(k) K093065 and K100947.

10. Non-Clinical Performance Data

Compatibility and stability studies have been completed that demonstrate the chemical, physical, microbiological stability and biocompatibility of insulin in the Finesse Insulin Delivery device for the period of time specified in the labeling. Design verification studies have been completed that demonstrate the wear and mechanical reliability of the device for the intended period of time. Design verification studies have been completed that demonstrate the usability and reliability of the Inserter accessory. Human factors and clinical evaluation studies have been completed that demonstrate device performance and usability.

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 and clinical evaluation testing.

12. Conclusions

The Finesse Insulin Delivery System is substantially equivalent in its intended use, performance, safety, effectiveness, underlying scientific and operating principles used and performs as well as or better than the predicate Finesse Insulin Delivery System (K093065 and K100947).

END OF SUMMARY

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

APR 10 2012

Mr. Richard J. Meader
Vice President Regulatory and Quality Affairs
Calibra Medical, Inc
220 Saginaw Drive
Redwood City, California 94063

Re: K111924
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: April 5, 2012
Received: April 6, 2012

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. 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,
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 adult 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)

for RZC Apr 11, 2012

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

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