9 510(k) Summary

510(k) Summary as Required by 21 CFR §807.92(c)

As required by the Safe Medical Devices Act (SMDA) of 1990 and in accordance with 21 CFR §807.92(a), the 510(k) summary provided below is of sufficient detailed to provide an understanding of the basis for a determination of substantial equivalence.

510(k) Summary

[807.92 (a)(1,2)]

Date Summary Prepared	September 25, 2013
510(k) Sponsor Address	Facet Technologies, LLC 112 Town Park Drive, Suite 300 Kennesaw, Georgia 30144
Contact Person	Mary Ann Kinard Senior Regulatory Affairs Manager Phone: (770) 590-6462 FAX: (770) 590-6412 Email:MaryAnn_Kinard@facettechnologies.com
Trade Name	CareFine™ Pen Needles
Common Name	Insulin Pen Needle
Classification Name	Needle, Hypodermic, Single Lumen
Regulation Number	21 CFR §880.5570
Product Code	FMI
Device Classification	II
Review Panel	80 General Hospital

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Predicate Marketed Devices:

[807.92(a)(3)]

Manufacturer	Trade Name	510(k) Number
UltiMed, Inc.	UltiCare® Disposable Pen	K100812
Novo Nordisk, Inc.	FlexPen®	K090111
Becton Dickinson	BD Pen Needle	K100005

[(807.92(a)(4)]

Description of Device:

CareFine™ Pen Needles are single use, sterile medical devices designed to be used in conjunction with pen injectors and pen cartridges for the subcutaneous injection of insulin. Pen needles are used by consumers, caregivers and health care professionals. They are offered in various gauge sizes (29G, 30G, 31G and 32G) and lengths (4mm, 5mm, 6mm, 8mm, and 12.7mm). CareFine™ Pen Needles are sterile (EtO terminal sterilization), non-toxic and non-pyrogenic.

The pen needle assembly consists of a doubled-ended cannula that is assembled into an injection molded hub using adhesive. The hub has internal threads, which allow it to be screwed onto the pen injector device. This allows the cartridge end of the cannula to penetrate through the rubber septum of the cartridge. The patient-end and the cartridge-end of the cannula are lubricated using a silicone based lubricant for ease of injection and rubber septum penetration.

An injection-molded inner shield is assembled over the patient-end of the cannula to protect the point from damage and accidental needle-sticks. This needle assembly is inserted into a protective injection-molded outer cover and sealed with a peel-away label to provide a sterility barrier and tamper evidence seal. The peel-away label is pre-printed with information, which includes the lot number and needle gauge and length.

The individual needle assemblies are packaged in cartons, and placed into shippers with appropriate labeling. The shipper cases are palletized and sterilized to a SAL of 10^{-6} by EtO terminal sterilization.

[(807.92(a)(5)]

Indication for Use:

The CareFine™ Pen Needle is intended for use with a pen injector device for the subcutaneous injection of insulin.

[(807.92(a)(6)]

Technological Characteristics:

The CareFine™ Pen Needles are substantially equivalent to the UltiCare®, Flex Pen®, and BD Pen Needles in terms of indications for use, compositions, material and design. Specifically, the following comparisons were made to determine equivalence of the CareFine™ Pen Needle to the referenced predicate pen needles:

- Needle sharpness,
- length, gauge,
- needle shield color(s),
- needle shield dimensions,
- needle shield strength,
- hub/needle bond strength,
- biocompatibility, materials and
- sterility

The CareFine™ Pen Needle product family is equivalent to the predicate devices, given that it:

- Does not modify the indication for use or any labeling change that affects the intended use of the device,
- Does not alter the fundamental scientific technology,
- Uses the same operating principles,
- Is manufactured from the same/similar materials,
- Is sterilized with a resulting SAL of 10^{-6}, and
- Is packaged using same/similar unit and case materials.

Based on the comparisons described above to the predicate comparator devices, the CareFine™ Pen Needles do not raise any new issues of safety and effectiveness.

[(807.92(b)(1)]

Non-Clinical Performance Data:

The CareFine™ Pen Needle is manufactured in accordance with the requirements of the current Current Good Manufacturing Practices for Medical Devices and the testing performed which support a determination of substantial equivalence includes:

- appropriate biocompatibility tests,
- sterility tests,
- predicate product comparative tests and

- performance tests.

The test results are in compliance with existing domestic and international standards. Based on the above test parameter results, the CareFine™ Pen Needles do not raise any new issues of safety and effectiveness.

[(807.92(b)(2)]

Clinical Performance Data:

Clinical data is not required.

[(807.92(b)(3)]

Conclusion:

Based on the design equivalency and the functional testing performed, Facet Technologies has determined that CareFine™ Pen Needles are equivalent to the predicate comparator devices currently cleared for marketing in the United States. Differences between the devices do not raise any significant issues of safety and effectiveness.

[(807.92(d)]

Other Information:

None

End of 510(k) Summary

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 23, 2014

Facet Technologies, LLC
Ms. Mary Ann Kinard
Senior Regulatory Affairs Manager
112 Town Park Drive, Suite 300
Kennesaw, GA 30144

Re: K133100
Trade/Device Name: CareFine™ Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: December 19, 2013
Received: December 20, 2013

Dear Ms. Kinard:

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 contact 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. 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,

Kwame O. Ulmer -S

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133100

Device Name
CareFine™ Pen Needles

Indications for Use *(Describe)*
The CareFine™ Pen Needle is intended for use with a pen injector device for the subcutaneous injection of insulin.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sajjad H. Syed -S

Digitally signed by Sajjad H. Syed -S
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