K101196

AUG 27 2010

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter

Submitted by:
Roche Diabetes Care AG
Kirchbergstrasse 190, Postfach
CH-3401 Burgdorf, Switzerland

United States Contact Person:
Scott Thiel
Roche Diagnostics
9115 Hague Road
Indianapolis, Indiana 46250
317-521-3362
scott.thiel@roche.com

Date Prepared: April 27, 2010

Device name

Proprietary name: ACCU-CHEK® Ultraflex infusion set
Common name: subcutaneous infusion set
Classification name: intravascular administration set
Product Code: FPA
Regulation number: 21 CFR 880.5440; Class II

Identification: An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

Predicate device

We claim substantial equivalence to the current legally marketed ACCU-CHEK® Ultraflex infusion set cleared under K#070189, concurrence received on February 21, 2007.

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510(k) Summary, Continued

Device description	The ACCU-CHEK® Ultraflex is a disconnectable infusion set with soft cannula perpendicular to the adhesive, for transfusion of insulin into the subcutaneous tissue. The unit is designed to interface with commercially available insulin infusion pumps with suitable connections. The insulin infusion pump systems are designed to control the delivery of insulin as prescribed by a health care professional. The system (infusion set, insulin infusion pump, and insulin) is indicated for patients with insulin dependent diabetes mellitus.
Intended use	ACCU-CHEK® Ultraflex is an infusion set for the subcutaneous infusion of insulin administered with micro dosage insulin pumps.

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510(k) Summary, Continued

Device Comparisons

The modified ACCU-CHEK® Ultraflex infusion set was compared to the current (predicate) ACCU-CHEK® Ultraflex infusion set. The modified ACCU-CHEK® Ultraflex is substantially equivalent to this product by having the same intended use, same storage conditions, same operating conditions, a luer connector, a flexible catheter and needle for insertion into the subcutaneous tissue and separate extension tubing with detachable connector. Both sets have an adhesive patch that secures the headset to the skin. Prior to infusion, both sets require removal of the introducer needle.

Transfer of manufacturing of the infusion set to a new manufacturer, Unomedical A/S, implied minor design modifications to the original model. The purpose of all modifications is to use components and manufacturing processes for the ACCU-CHEK® Ultraflex Infusion set that are already established at Unomedical and used for manufacture of other commercially available infusion sets.

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Summary of Studies

Functional Testing:

In vitro functional testing of the ACCU-CHEK® Ultraflex infusion set was conducted. Biocompatibility testing was performed on the materials used in both devices.

Clinical Studies:

Human clinical studies were not deemed necessary to evaluate the safety or effectiveness of the ACCU-CHEK® Ultraflex infusion set.

Study Conclusions

Functional Testing:

The results of the testing conducted indicate the ACCU-CHEK® Ultraflex infusion set functioned according to specifications and the materials used in the devices are biocompatible.

Based upon these results, the product is considered acceptable for human 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

Mr. Scott Thiel
Regulatory Affairs Program Manager
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, Indiana 46250

AUG 27 2010

Re: K101196
Trade/Device Name: ACCU-CHEK® Ultraflex infusion set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: August 9, 2010
Received: August 10, 2010

Dear Mr. Thiel:

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,

Susan Runner

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

K101196

Indications for Use Statement

510(k) Number (if known):

Device Name: ACCU-CHEK® Ultraflex infusion set

Indications for Use:

ACCU-CHEK® Ultraflex is an infusion set for the subcutaneous infusion of insulin administered with micro dosage insulin pumps.

Prescription Use _XXX__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Susan Runner

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

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