DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 13, 2015

Mr. Alexander Rügner
Regulatory Affairs Manager
Roche Diagnostics GmbH
Sandhofer Strasse 116
Mannheim, Germany, 68305

Re: K143446
Trade/Device Name: ACCU-ChEK® FlexLink Plus infusion set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: II
Product Code: FPA
Dated: July 8, 2015
Received: July 9, 2015

Dear Mr. Rügner:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Erin I. Keith -S

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143466

Device Name
ACCU-CHEK FlexLink Plus Infusion Set

Indications for Use *(Describe)*

ACCU-CHEK FlexLink Plus is an infusion set for the subcutaneous infusion 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary K143446

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

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Date Prepared: November 20, 2014

Device name

Proprietary name: ACCU-CHEK® FlexLink Plus Infusion Set
Common name: subcutaneous infusion set
Classification name: intravascular administration set
Regulation number: 21 CFR §880.5440
Product Code: FPA

Predicate device

We claim substantial equivalence to the cleared predecessor Accu-Chek FlexLink Plus (K#100704) infusion set

Device description

The ACCU-CHEK® FlexLink Plus 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.

510(k) Summary K143446, Continued

Intended use

ACCU-CHEK® FlexLink Plus is an infusion set for the subcutaneous infusion of insulin.

Data demonstrating substantial equivalence

Testing demonstrated that the device meets the requirements for its intended use. The data also demonstrates substantial equivalence to the predicate device.

The slight difference (omit "administered with micro dosage insulin pump") of the indication for use between the modified Accu-Chek FlexLink Plus and the predicate device does not affect the intended use. The infusion set intended for subcutaneous infusion of insulin is a default accessory used together with a micro dosage insulin pump. Functional testing to verify the intended use of the modified Accu-Chek FlexLink Plus was conducted together with micro dosage insulin pumps.

Dimensional characteristics of the predicate as compared to the current subject device are listed below:

Feature	Predicate (K#100704)	Current subject device (K#143446)
Name	ACCU-CHEK FlexLink Plus	ACCU-CHEK FlexLink Plus
Tube length	40, 70, 100 cm	Same
Needle length (to grind start)	17.8, 19.8 or 21.8mm	19.63, 21.63 or 23.23mm
Needle diameter	0.36mm	0.40mm
Soft cannula length	6mm / 8mm / 10mm	Same
Soft cannula length (actual)	8.6, 10.5 or 12.5mm	8.5, 10.5 or 12.1mm
Soft cannula (ID/OD) **Wall thickness**	0.4mm/0.62mm 0.11mm	0.44 mm/0.68mm 0.12mm
Distance Cannula tip to needle end	0.7 mm	2.43 mm
Priming volume (average for tube set + 1 IU for priming head set)	7 U, 11 U, 15 U* *U 100 insulin	Same
Tubing ID/OD	0.4 mm x 1.47 mm	Same

Storage conditions	-20°C to +50 °C -4°F to +122°F	+5 °C to +45°C +41 °F to +113°F
Operating conditions	+5 °C to +45°C +41 °F to +113°	Same
Connector	Luer connector	Same
Sterilization methodology	Ethylen Oxide	Same
Prescription use only	Prescription use only	Same
Single use	Single use	Same

Standard used in testing	ISO 7864: 1993	Sterile hypodermic needles for single use
	AAMI/ANSI/ISO 10993-1: 2003,	Biological evaluation of medical devices - part 1: evaluation of testing
	AAMI/ANSI/ISO 10993-7: 2008	Biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals
	AAMI/ANSI/ISO 11135-1:2007	Sterilization of healthcare products-ethylene oxide-part1:requirements for the development
	AAMI/ANSI/ISO 11607-1:2006	Packaging for terminally sterilized medical devices-part1-requirements for materials, sterile
	AAMI/ANSI/ISO 11607-2: 2006	Packaging for terminally sterilized medical devices-part 2-Validation requirements for forming
	IEC 62366: 2007	Medical devices - application of usability engineering to medical devices

Device comparisons

The ACCU-CHEK FlexLink Plus infusion set is compared to its predicate device (K#100704). The ACCU-CHEK FlexLink Plus is substantially equivalent to the predicate by having the same intended use, same operating conditions, same luer connector, a flexible cannula and needle for insertion into the subcutaneous tissue and separate extension tubing with a detachable connector. Both sets have an adhesive patch that secures the headset to the skin. Both sets incorporate a needle protection feature that retracts the needle automatically following insertion of the needle and cannula.

Summaries of Studies

In vitro functional testing of the ACCU-CHEK FlexLink Plus infusion set was conducted. Biocompatibility testing was performed on the materials used in the device

System validation testing included human factors usability testing of the requirements and primary operating function of the ACCU-CHEK FlexLink Plus infusion set. Individuals who participated in the evaluation included patients who routinely use insulin pump and infusion set. The usability evaluation determined the customer requirements and the primary operation functions were met.

Clinical studies:
Human clinical studies were not deemed necessary to evaluate the safety of effectiveness of the ACCU-CHEK FlexLink Plus infusion set.

Study conclusion

The results of the *in vitro* testing conducted indicate the ACCU-CHEK FlexLink Plus infusion set function according to their specification and the device materials are biocompatible.
The design validation confirmed that the device fulfills its intended use, customer requirement and primary operating functions.

Based on the comparison above, the proposed device, ACCU-CHEK® FlexLink Plus infusion set, is determined to be Substantially Equivalent (SE) to the predicate devices.