K122370

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Bayer Healthcare, Diabetes Care
Address	430 S Beiger St Mishawaka IN 46544
Phone number	574-256-3441
Fax number	547-256-3519
Establishment Registration Number	1826988
Name of contact person	Roger Sonnenburg
Date prepared	08/03/2012
Name of device	
Trade or proprietary name	Contour® NEXT LINK Wireless Blood Glucose Meter
Common or usual name	Blood Glucose Meter
Classification name	75 LFR Glucose Dehydrogenase, Glucose
Classification panel	Clinical Chemistry and Toxicology
Regulation	21 CFR 862.1345
Product code(s)	LFR (Glucose Dehyrogenase, Glucose), NBW (System, Test, Blood Glucose, Over The Counter)
Legally marketed device(s) to which equivalence is claimed	K110894 Contour® NEXT LINK Wireless Blood Glucose Meter
Reason for 510(k) submission	This submission is to add a Medtronic MiniMed pump, the 530G, to the list of Medtronic devices listed in the Indications for Use
Device description	The Contour® NEXT LINK Wireless Blood Glucose Monitoring System consists of a blood glucose meter, dry test strips and liquid controls to be used for the measurement of glucose in capillary whole blood by persons with diabetes. The System has the same automatic calibration as the predicate device. Blood glucose results are displayed on the meter window and stored in the meter's memory. The System also contains radio frequency (RF) functions for sending BGM results to compatible Medtronic MiniMed insulin pumps. The RF function can also serve as a pass through for data being transmitted from Medtronic MiniMed insulin pumps to Medtronic's MiniMed PC-based data management software.

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Intended use of the device	See indications for use below
Indications for use	The Contour NEXT LINK Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The Contour NEXT LINK Wireless Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. Contour NEXT Test Strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL. The Contour NEXT LINK Wireless Blood Glucose Monitoring System is intended to be used to transmit glucose values to Medtronic MiniMed Paradigm Insulin Pumps or Medtronic MiniMed Paradigm REAL-Time Revel Insulin Pumps or Medtronic MiniMed Paradigm REAL-TIME Insulin Pumps or Medtronic MiniMed 530G Insulin Pumps or Guardian REAL-TIME Monitor and facilitate transfer of information to Medtronic MiniMed Carelink Therapy Management Software through use of radio frequency communication. The Contour NEXT LINK Wireless Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

Similarities to Predicate Device		
Characteristic	**Predicate Device Contour NEXT LINK Wireless K110894**	**New Device Contour NEXT Link Wireless**
Test Strip	Contour NEXT Test Strip	Same as predicate
Algorithm	Multi-pulse algorithm	Same as predicate
User interface	Alphanumeric, Iconic, Native Language	Same as predicate
Number of buttons	4	Same as predicate
Display (technology)	Graphical (OLED)	Same as predicate
Radio-frequency communication	Yes	Same as predicate

Differences from Predicate Device		
Characteristic	**Predicate Device** **Contour NEXT Link Wireless** **K110894**	**New Device** **Contour NEXT Link Wireless**
Indications for Use	Includes the following Medtronic devices: Medtronic MiniMed Paradigm Insulin Pumps or Medtronic MiniMed Paradigm REAL-Time Revel Insulin Pumps or Medtronic MiniMed Paradigm® REAL-TIME Insulin Pumps or Guardian REAL-TIME Monitor.	Adds Medtronic MiniMed 530G Insulin Pump to the Indications for Use

VERIFICATION AND VALIDATION DATA

Please refer to PMA submission P120010 for verification and validation reports on the performance of the Contour NEXT Link Wireless Blood Glucose Meter with the Medtronic MiniMed 530G Insulin Pump.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The performance of the Contour NEXT LINK Wireless Blood Glucose Monitoring System is substantially equivalent to the performance of the previously cleared Contour NEXT LINK Wireless Blood Glucose Monitoring System (K110894).

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

September 26, 2013

Bayer Healthcare
c/o Mr. Roger Sonnenburg
430 Sourth Beiger St.
MISHAWAKA IN 46544

Re: K122370
Trade/Device Name: Contour Next Link Wireless Blood Glucose Monitor
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: September 20, 2013
Received: September 23, 2013

Dear Mr. Sonnenburg:

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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), 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,

Courtney H. Lias, Ph.D.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122370

Device Name: Contour® NEXT LINK Wireless Blood Glucose Monitoring System

Indications For Use:

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Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___x____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

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