



September 23, 2015

BAYER HEALTHCARE
JENNIFER GREGORY
PRINCIPAL REGULATORY AFFAIRS SPECIALIST
430 SOUTH BEIGER STREET
MISHAWAKA IN 46544

Re: K151742

Trade/Device Name: Contour Next Control Solution

Regulation Number: 21 CFR 862.1660

Regulation Name: Quality Control Material (assayed and unassayed)

Regulatory Class: I, reserved

Product Code: JJX

Dated: July 24, 2015

Received: July 27, 2015

Dear Ms. Gregory:

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 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” (21 CFR 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,


Katherine Serrano -S

FOR: 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)

K151742

Device Name

CONTOUR@NEXT Control Solution

Indications for Use (Describe)

CONTOUR@NEXT control solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check to ensure that the Contour Next Blood Glucose Monitoring Systems are working properly.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date prepared: September 3, 2015

According to the requirements of 21 CFR 807.92, the following information is being submitted in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.

- 1) Submitter Jennifer Gregory
Principal Regulatory Affairs Specialist
Bayer Healthcare LLC
430 South Beiger Street
Mishawaka, IN 46544
Telephone: (574) 256-3447
Fax: (574) 256-3519
- 2) Device name: Trade name: Contour® Next Control Solution
Common name: Control Solution
Classification name: Quality Control Material, 75 JJX (21 CFR 862.1660)
- 3) Predicate device: Contour Next Control Solution (Reference: Contour Next EZ Blood Glucose Monitoring System (K111268))
- 4) Device description: Contour Next Control Solution is used as a quality control check to assure the customer that their Bayer Contour Next blood glucose monitoring system is reading accurately. The control solution has a very controlled amount of glucose in it. The bottles of Contour Next test strips have a range of acceptable values on every bottle that is used to compare the result obtained when the control solution is applied to the test strip. When the reading from the control solution is within the range on the bottle, the system has been quality control checked and shown to be accurate. If the reading from the control solution is outside the stated range, then the customer is instructed by the user guide to not use the system until trouble-shooting can be done and/or customer service is called for help.
- 5) Intended Use: CONTOUR®NEXT control solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check to ensure that the Contour Next Blood Glucose Monitoring Systems are working properly.



Data demonstrating substantial equivalence

The Contour Next Control Solution is a quality control material used to ensure a customer’s Contour Next blood glucose monitoring system is reading accurately and is substantially equivalent to the predicate Contour Next Control Solution (reference K111268 Contour Next EZ Blood Glucose Monitoring System).

The Solution is a prescribed amount of glucose in water and includes a buffer, red dye, and a thickening agent. The control solution comes in a 2.5mL plastic bottle with an applicator tip. It comes in two glucose levels, Level 1 (about 45mg/dL) and Level 2 (about 125mg/dL).

No technological changes have been made to the system since the previous submission, K111268.

A detailed comparison of the composition of the modified and predicate control solutions is provided in the tables below:

Modified Control Solution
(Contour Next Control Solution)

Predicate Control Solution
(Contour Next Control Solution)



Bottle label for modified control

Bottle label for predicate control



Composition of the Modified Control Solution Compared to Predicate	
SIMILARITIES to Predicate	
Composition of Predicate Contour Next Control Solution (K111268)	Composition of Modified Contour Next Control Solution
Buffer	Same as Predicate
Coloring Agent	Same as Predicate
Thickening Agent	Same as Predicate
Preservative	Same as Predicate
Glucose	Same as Predicate



DIFFERENCES from Predicate		
Composition/Characteristics	Predicate	Modified Control Solution
	Contour Next Control Solution (K111268)	Contour Next Control Solution
Surfactant	No	Yes
Control test temperature range	5C-45C	15C-35C
Glucose Concentration	0.025% (level 1) 0.067% (level 2)	0.03% (level 1) 0.07% (level 2)
Inactive ingredients	99.975% (level 1) 99.933% (level 2)	99.97% (level 1) 99.93% (level 2)
Instructions to “Shake well, about 15 times” on control bottle label and “Shake control 15 times before every use” in product insert	No	Yes
Addition of warning statements to product insert: <ul style="list-style-type: none"> • Unmixed control solution may cause inaccurate control results • Do not calibrate your continuous glucose monitoring device from a control result • Do not calculate a bolus based on a control result 	No	Yes



Summary of Performance testing

Bench testing conducted showed that the modified Contour Next Control Solution performed as intended and met the system specifications.

Stability testing was conducted to ensure the modifications did not impact the shelf-life or use-life claims for the Contour Next Control Solution. The results of the testing showed there was no impact to the claimed shelf-life or use-life.

Usability testing was conducted to ensure that the modified solution did not impact the ability of end users to perform a control test. The results of the testing showed there was no impact in the ability of end users to perform control tests using the modified solution.

Conclusions from Performance Evaluations

Based on the outcome of the performance testing conducted, the modified Contour Next Control Solution is substantially equivalent to the predicate Contour Next Control Solution (K111268).