December 23, 2021

Ascensia Diabetes Care
Colleen Burdel
Manager, Regulatory Affairs
100 Summit Lake Drive
Valhalla, New York 10595

Re: K193407
    Trade/Device Name: Contour® next GEN Blood Glucose Monitoring System
    Regulation Number: 21 CFR 862.1345
    Regulation Name: Glucose Test System
    Regulatory Class: Class II
    Product Code: NBW
    Dated: November 12, 2020
    Received: November 13, 2020

Dear Colleen Burdel:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combatination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K193407

Device Name
Contour® next GEN Blood Glucose Monitoring System

Indications for Use (Describe)
The Contour® next GEN Blood Glucose Monitoring System consists of the Contour® next GEN meter, Contour® next test strips and the Contour® Diabetes app.

The Contour® next Gen Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips. The Contour® next GEN Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Contour® next GEN Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program.

The Contour® next GEN Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use.

The system is intended for in vitro diagnostic use only.

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

510(k) number: k193407

Date prepared: December 22, 2021

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
Colleen Burdel
Head of Product - Regulatory Affairs
Ascensia Diabetes Care
100 Summit Lake Drive
Valhalla, NY 10595
Phone: 914-296-2880
Email address: colleen.burdel@ascensia.com

2) Device name:
Trade name: Contour® next GEN Blood Glucose Monitoring System
Common name: Blood Glucose Meter
Classification name: 75 NBW; Glucose Test System, OTC

3) Predicate device:
Contour® Next ONE Blood Glucose Monitoring System (K160682)

4) Device description:
Contour® next GEN Blood Glucose Monitoring System is a blood glucose meter with Bluetooth Low Energy technology built in so that the meter can communicate wirelessly to smart phones and tablets. The meter uses the Contour® next test strips and Contour® next control solution. The meter can be connected to the Contour® Diabetes app. It utilizes a similar algorithm as the one used in the Contour® next ONE blood glucose meter. It uses two replaceable CR2032 coin cell batteries. The meter’s shape is a traditional oval form factor and it includes an illuminated strip port with colors indicating if a glucose result is above, within, or below target.
5) Intended Use: The Contour® next GEN Blood Glucose Monitoring System consists of the Contour® next GEN meter, Contour next test strips and the Contour Diabetes app.

The Contour® next GEN Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips. The Contour® next GEN Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Contour® next GEN Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program.

The Contour® next GEN Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use.

The system is intended for in vitro diagnostic use only.
Data demonstrating substantial equivalence

A detailed comparison of the modified device and predicate device is provided in the tables below:

**Table of Similarities between Contour® next GEN to Contour® next ONE (k160682):**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Contour® next ONE (Predicate Device; k160682)</th>
<th>Contour® next GEN (Subject Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test strip</td>
<td>CONTOUR® NEXT Test strips</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Test strip chemistry</td>
<td>FAD-GDH (MLB as the mediator)</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Blood sample volume</td>
<td>0.6μL</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Test count-down time</td>
<td>5 seconds</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Applied voltage pattern</td>
<td>Multi-pulse</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Glucose range</td>
<td>20-600 mg/dL</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Controls</td>
<td>CONTOUR® NEXT Control</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Control solution ranges</td>
<td>Level 1 and 2</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Battery type</td>
<td>CR 2032</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Automatic calibration</td>
<td>Yes</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Enhanced error detection for test strips exposed to a reducing agent</td>
<td>Yes</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Enhanced error detection for control solution not mixed</td>
<td>Yes</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Enhanced error detection for perturbed test strips</td>
<td>Yes</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Wireless Technology</td>
<td>Bluetooth Low Energy to smart phones and tablets</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>PC Connection</td>
<td>Micro-USB Port</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Test Memory</td>
<td>800 Results</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Color Indicator for Above/Below Target</td>
<td>Illuminated strip port, with colors, indicating whether a glucose result is above, within, or below target</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Sample re-application capability</td>
<td>60-second re-application time</td>
<td>Same as predicate</td>
</tr>
<tr>
<td>Compatibility with CONTOUR® DIABETES app</td>
<td>Yes</td>
<td>Same as predicate</td>
</tr>
</tbody>
</table>
Table of Differences between Contour® next GEN and Contour® next ONE (k160682):

<table>
<thead>
<tr>
<th>Feature</th>
<th>Contour® next ONE (Predicate Device; k160682)</th>
<th>Contour® next GEN (Subject Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form Factor</td>
<td>Rectangular Shape</td>
<td>Traditional Oval Shape</td>
</tr>
<tr>
<td>Algorithm</td>
<td>Multiple regression equations</td>
<td>Modified terms in the equations</td>
</tr>
<tr>
<td>Buttons</td>
<td>1 center button with up/down rocker button</td>
<td>1 'OK' button with up/down rocker button</td>
</tr>
<tr>
<td>Display</td>
<td>LCD with 7-segments and icons</td>
<td>Non-back lit, segmented display</td>
</tr>
<tr>
<td>Test Result Trends</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>(Averages)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Reminders</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Meal markers</td>
<td>Pre-meal, post-meal, fasting and no mark</td>
<td>Pre-meal, post-meal, and no mark</td>
</tr>
<tr>
<td>Bluetooth (Low Energy)</td>
<td>4.1</td>
<td>4.2</td>
</tr>
<tr>
<td>Version</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Contour® next ONE Blood Glucose Meter (Predicate Device)

Contour® next GEN Blood Glucose Meter (Subject Device)
Summary of Performance Testing

Clinical trials and bench testing showed that the Contour® next GEN Blood Glucose Monitoring System performed as intended and met the system specifications.

Usability testing was conducted to ensure that the Contour® next GEN Blood Glucose Monitoring System was easy to use by typical customers.

Conclusions from Performance Evaluations

Based on the outcome of the performance testing conducted, the Contour® next GEN Blood Glucose Monitoring System is substantially equivalent to the predicate Contour® next ONE Blood Glucose Monitoring System (k160682).