February 14, 2017

Medtronic Inc.
Laura Danielson
Principal Regulatory Affairs Specialist
8200 Coral Sea St NE
Mounds View, Minnesota 55112

Re: K163460
  Trade/Device Name: Reveal LINQ Insertable Cardiac Monitor, Model LNQ11
  Regulation Number: 21 CFR 870.1025
  Regulation Name: Arrhythmia Detector and Alarm
                   (Including ST-Segment Measurement and Alarm)
  Regulatory Class: Class II
  Product Code: DSI
  Dated: December 8, 2016
  Received: December 9, 2016

Dear Laura Danielson:

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" (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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

The Reveal LINQ ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia

The device has not been tested specifically for pediatric use.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)
Summary of Substantial Equivalence
The intended use, design, materials and performance of the Reveal LINQ ICM (Model LNQ11) in association with the LINQ Mobile Manager Application (Model MSW001 or MSW002) and patient connector (Model 24965 and 24967) (referred to as the LINQ Mobile Manager system) are substantially equivalent to the following predicate device:

- Reveal LINQ ICM (Model LNQ11) cleared via K160689 on April 22, 2016.

Indications for Use Comparison to the Predicate
The indications for use remains unchanged from the predicate and are as follows:

The Reveal LINQ ICM is an insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia

The device has not been tested specifically for pediatric use.
Comparison of Technological Characteristics with Predicate Device

The following table contains a comparison of the CareLink SmartSync Device Manager patient connector, Model 24967 to the predicate device (Model 24965) with no differences.

### Predicate Comparisons

<table>
<thead>
<tr>
<th>Feature</th>
<th>Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 or MSW002 and existing patient connector Model 24965)</th>
<th>Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 and MSW002 and additional patient connector Model 24967)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Medtronic, Inc.</td>
<td>Medtronic, Inc.</td>
</tr>
<tr>
<td>510(k) Number</td>
<td>K160809</td>
<td>KXXXXXXX</td>
</tr>
<tr>
<td>Model Number</td>
<td>LNQ11</td>
<td>LNQ11</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Same (See Indications for Use Form 3881)</td>
<td>Same (See Indications for Use Form 3881)</td>
</tr>
<tr>
<td>Ambulatory ECG Monitor</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Continually Record ECG Information?</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Record Pre- &amp; post-event</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>R Wave Sensing Sampling Rate</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Storage Time</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Noise Reversion</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Brady Detection</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Asystole Detection</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Ventricular Tachycardia Detection</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Patient Activated &amp; Auto Activated</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Atrial Tachyarrhythmia Monitoring &amp; Diagnostics</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Day &amp; Night Heart Rate Diagnostics</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Afib Detection</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Heart Rate Variability Algorithm &amp; Diagnostics</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Telemetry</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Activity Monitoring</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Longevity</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Electrode Spacing (inside-to-inside)</td>
<td>Same</td>
<td>Same</td>
</tr>
</tbody>
</table>
The following patient contacting material comparison demonstrates substantial equivalence between patient contacting materials. Information on differences can be found in the paragraph following the table.

**Patient Contacting Material Comparison**

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
<th>Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 or MSW002 and existing patient connector Model 24965)</th>
<th>Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 and MSW002 and additional patient connector Model 24967)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can</td>
<td>Titanium</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Electrodes</td>
<td>Titanium nitride</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Header</td>
<td>Polyurethane, silicone</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Coating</td>
<td>Parylene</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Component</td>
<td>Material</td>
<td>Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 or MSW002 and existing patient connector Model 24965)</td>
<td>Reveal LINQ ICM Model LNQ11 (with existing LINQ Mobile Manager Application Models MSW001 and MSW002 and additional patient connector Model 24967)</td>
</tr>
<tr>
<td>------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Telemetry Head</td>
<td>Amorphous thermal plastics, thermal plastic elastomer, silicone rubber and polyester film</td>
<td>Polycarbonate Lexan</td>
<td>Silicone rubber Rogers Bisco HT-6240, clear Polycarbonate Sabic Lexan EXL9330 with 8T9D168 white colorant (Medtronic color chip M954239A001) Silicone rubber Wacker Elastosil LR 3003/60, color chip SP 50812 (blue) Silicone rubber Momentive TSE221 per color chip Pantone Cool Grey 8 button; polyester Autotex V200 clear (back screened) with hard coated top surface and velvet finish graphics</td>
</tr>
</tbody>
</table>

**Telemetry Head Material**

The housing material of the CareLink SmartSync Device Manager patient connector is polycarbonate. The use of polycarbonate boosts chemical resistance concerning exposure to repeat cleaning and disinfection.

**Performance Data**

The following performance data were provided in support of the substantial equivalence determination.

**Biocompatibility Testing**

The biocompatibility evaluation for the CareLink SmartSync Device Manager, patient connector, Model 24967 was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The battery of testing for materials used in the Model 24967 included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The Model 24967 has acute duration of skin contact with the patient, and is not implanted.

**Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the CareLink SmartSync Device Manager, patient connector, Model 24967, associated applications and non-medical mobile platform (i.e. Tablet) with associated cables as necessary for test. The system complies with the IEC 60601-1, standards for safety and the IEC 60601-1-2 third and fourth edition versions of the standard for EMC.

**Software Verification and Validation Testing**

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “major” level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

**Mechanical Testing**

The following is a list of testing performed:

- Inspection of the required mechanical design features and function
- Workmanship inspection concerning all external surfaces that can cause injury such as sharp edges or pinch points
- Product labeling inspection
- Forces required to activate controls
- Chemical resistance testing for effects of repeat cleaning cycles
- Environmental and drop testing
- Reliability testing of buttons, electrical contacts, user connector insertions, and replaceable or moving mechanical components

**Animal Study**

There were no formalized animal studies performed for this 510(k) submission.

**Clinical Studies**

There were no formalized clinical studies performed for this 510(k) submission.

**Conclusions**

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the CareLink SmartSync Device Manager, patient connector, Model 24967 should perform as intended in the specified use conditions.