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

Geena George
Principal Regulatory Affairs Specialist
Medtronic MiniMed
18000 Devonshire St.
Northridge, CA 91325-1219

August 12, 2016

Re: P150001
MiniMed 630G System with SmartGuard™
Filed: January 9, 2015
Amended: February 2, 2015, March 17, 2015, August 27, 2015, August 31, 2015, September 4, 2015, February 29, 2016, April 4, 2016, May 2, 2016
Product Code: OZO, MDS, NBW, LFR

Dear Ms. George:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its review of your premarket approval application (PMA) and issued an approval order on August 10, 2016. We inadvertently made an error by including indications for use for your device system and its associated components that did not match the most up to date versions of these indications for use. Your device is indicated for the following:

MiniMed 630G System with SmartGuard
The MiniMed 630G System with SmartGuard™ is intended for continuous delivery of basal insulin (at user selected rates) and administration of insulin boluses (in user selectable amounts) for the management of diabetes mellitus in persons, sixteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 630G system includes SmartGuard™, which can be programmed to temporarily suspend delivery of insulin for up to two hours when the sensor glucose value falls below a predefined threshold value.

The MiniMed 630G System with SmartGuard™ consists of the following devices: MiniMed 630G Insulin Pump, Enlite® Sensor, One-press serter, Guardian® Link Transmitter System, CareLink® USB, Bayer's CONTOUR ® NEXT LINK 2.4 Wireless Meter, and Bayer's CONTOUR® NEXT Test Strips. The system requires a prescription.

The MiniMed 630G System with SmartGuard™ is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the MiniMed 630G system.

The MiniMed 630G System with SmartGuard™ is not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the SmartGuard™ Suspend on low alarm to take measures to prevent or treat hypoglycemia themselves. Therapy to prevent or treat hypoglycemia should be administered according to the recommendations of the user's healthcare provider.

Enlite® Sensor
The Enlite® Sensor is intended for use with Medtronic MiniMed Insulin pump (MMT-1715). It continuously monitors glucose levels in persons with diabetes.

One-press Serter
The One-press Serter is used as an aid for inserting the Enlite sensor. It is indicated as a single-patient use device and it is not intended for multiple-patient use.

Guardian® Link Transmitter System
The Medtronic MiniMed Guardian Link Transmitter is indicated for use as a component of select Medtronic continuous glucose monitoring and sensor-enabled pump systems. It processes, stores and transmits glucose sensor values to data collection and display devices. The Guardian Link Transmitter is not intended to function as a stand-alone device and is for single-patient use. The Guardian Link Transmitter System includes the Guardian Link Transmitter (MMT-7763), charger (MMT-7715), watertight tester (MMT-7726), and One-press serter (MMT-7512).

CareLink® USB
The Medtronic CareLink® USB is indicated for use by patients at home, and clinicians in a medical office setting, to facilitate communication between MiniMed 630G insulin pump and a personal computer. The computer must use Medtronic diabetic therapy management software.

Bayer CONTOUR® NEXT Link 2.4 Wireless Blood Glucose Glucose Monitoring System
The CONTOUR® NEXT Link 2.4 Wireless Blood Glucose Monitoring System is an over the counter (OTC) and/or prescription device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only. The CONTOUR® NEXT Link 2.4 wireless blood glucose monitoring system is indicated for use with fresh capillary whole blood samples (drawn from the fingertip or palm only). The CONTOUR® NEXT Link 2.4 Blood Glucose Meter can wirelessly connect to the MiniMed 630G pump through the use of radio frequency communication. The meter can transmit glucose values, be used as a remote control to facilitate delivery of a bolus of insulin from the insulin pump, and facilitate transfer of information from the pump to the Medtronic MiniMed data management software. The CONTOUR® NEXT Link 2.4 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.

We hope that this error has not inconvenienced you. If you have any questions about this corrective action, please contact Joshua Balsam at (240)-402-6521 or Joshua.Balsam@fda.hhs.gov.

Sincerely,

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

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Product Code: OZO, MDS, NBW, LFR

Dear Ms. George:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the MiniMed 630G System with SmartGuard. This device is indicated for the following:

MiniMed 630G System with SmartGuard
The MiniMed 630G System with SmartGuard™ is intended for continuous delivery of basal insulin (at user selected rates) and administration of insulin boluses (in user selectable amounts) for the management of diabetes mellitus in persons, sixteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 630G system includes SmartGuard™, which can be programmed to temporarily suspend delivery of insulin for up to two hours when the sensor glucose value falls below a predefined threshold value.

The MiniMed 630G System with SmartGuard™ consists of the following devices: MiniMed 630G Insulin Pump, Enlite® Sensor, Enlite® 1-Press Serter, Guardian® Link Transmitter System, CareLink® USB, Bayer's CONTOUR ® NEXT LINK 2.4 Wireless Meter, and Bayer's CONTOUR® NEXT Test Strips. The system requires a prescription.

The MiniMed 630G System with SmartGuard™ is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the MiniMed 630G system.

The MiniMed 630G System with SmartGuard™ is not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the SmartGuard™ suspend on low alarm to take measures to prevent or treat hypoglycemia themselves. Therapy to prevent or treat hypoglycemia should be administered according to the recommendations of the user's healthcare provider.

Enlite® Sensor
The Enlite® Sensor is intended for use with Medtronic MiniMed Insulin pump (MMT-1715). It continuously monitors glucose levels in persons with diabetes.

Enlite® 1-press Serter
The Enlite® 1-press Serter is used as an aid for inserting the Enlite sensor. It is indicated as a single-patient use device and it is not intended for multiple-patient use.

Guardian® Link Transmitter
The Medtronic MiniMed Guardian Link Transmitter is indicated for use as a component of select Medtronic continuous glucose monitoring and sensor-enabled pump systems. It processes, stores and transmits glucose sensor values to data collection and display devices. The Guardian Link Transmitter is not intended to function as a stand-alone device and is for single-patient use.

CareLink® USB
The Medtronic CareLink® USB is indicated for use by patients at home, and clinicians in a medical office setting, to facilitate communication between MiniMed 630G insulin pump and a personal computer. The computer must use Medtronic diabetic therapy management software.

Bayer CONTOUR® NEXT Link 2.4 Wireless Blood Glucose Glucose Monitoring System
The CONTOUR® NEXT Link 2.4 Wireless Blood Glucose Monitoring System is an over the counter (OTC) and/or prescription device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only. The CONTOUR® NEXT Link 2.4 wireless blood glucose monitoring system is indicated for use with fresh capillary whole blood samples (drawn from the fingertip or palm only). The CONTOUR® NEXT Link 2.4 Blood Glucose Meter can wirelessly connect to the MiniMed 630G pump through the use of radio frequency communication. The meter can transmit glucose values, be used as a remote control to facilitate delivery of a bolus of insulin from the insulin pump, and facilitate transfer of information from the pump to the Medtronic MiniMed data management software. The CONTOUR® NEXT Link 2.4 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.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act

(the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for the CGM Sensor component of this device has been established and approved at 6 months at storage conditions between 36ºF to 86ºF. Expiration dating for the Insulin Pump component of this device has been established and approved at 6 months. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the

labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

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If you have any questions concerning this approval order, please contact Joshua Balsam at 240-402-6521 or Joshua.Balsam@fda.hhs.gov.

Sincerely,

Courtney H. Lias -S

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Director
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Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health