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

Ms. Lusin Markaryan
Manager, Regulatory Affairs
Medtronic, Inc.
18000 Devonshire Street
Northridge, CA 91325-1219

Re: P120010
MiniMed 530G System
Filed: June 5, 2012
Amended: June 22, 2012, August 3, 2012, August 23, 2012, October 17, 2012, April 11, 2013, and July 16, 2013
Procode: OZO

Dear Ms. Markaryan:

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 530G System. This device is indicated for the following:

MiniMed 530G System
The MiniMed 530G System is intended for continuous delivery of basal insulin (at user selectable 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 530G System can be programmed to automatically suspend delivery of insulin when the sensor glucose value falls below a predefined threshold value.

The MiniMed 530G System consists of the following devices that can be used in combination or individually: MiniMed 530G Insulin Pump, Enlite™ Sensor, Enlite™ Serter, the MiniLink Real-Time System, the Bayer Contour NextLink glucose meter, CareLink® Pro Therapy Management Software for Diabetes, and CareLink® Personal Therapy Management Software for Diabetes. The system requires a prescription.

The MiniMed 530G System 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 530G System.

The MiniMed 530G System 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 Threshold Suspend alarm to take measures to prevent or treat hypoglycemia himself. Therapy to prevent or treat hypoglycemia should be administered according to the recommendations of the user's Health Care Provider.

Enlite® Sensor
The Enlite Sensor is intended for use with Medtronic MiniMed 530G Insulin pump (models MMT-551, MMT-751) to continuously monitor glucose levels in persons with diabetes.

Enlite® Serter
The Enlite 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.

CareLink® Pro
CareLink Pro is designed to enhance Health Care Provider management of diabetic patients using Medtronic insulin pumps and glucose monitors and is intended for use as a tool to help manage diabetes. The purpose of this system is to take information transmitted from insulin pumps, glucose meters and continuous glucose monitoring systems, and turn it into CareLink Pro reports. The reports provide information that can be used to identify trends and track daily activities—such as carbohydrates consumed, meal times, insulin delivery and glucose readings.

CareLink® Personal
CareLink Personal is intended for use within the home and Health Care Provider environments. CareLink Personal is intended for use as a tool to help control diabetes. The purpose of this system is to take information transmitted from insulin pumps, continuous glucose monitors and glucose meters, and logbook data entered by the patient, and turn it into CareLink Personal reports.

MiniLink Real-Time System
The MiniLink Real Time System consists of the MiniLink Transmitter, a tester and a charger. When connected to a sensor that is inserted in the body, the transmitter automatically initializes the sensor and begins to periodically send glucose data to the pump using a radio signal.

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.

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.

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.

In addition to the Annual Report requirements, you must provide the following data in post-approval study reports (PAS). Two (2) copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below.

Post Approval Study of the TS (Threshold Suspend) Feature with a Sensor-Augmented Pump System:

This study will be conducted as per protocol dated July 28, 2013, Version CEP266/Z25/J. The study objective is to demonstrate that home use of Threshold Suspend (TS) is not associated with glycemic deterioration, with the mean changes of hemoglobin A1C (HbA1c) less than 0.4%. The study is a longitudinal, multi-center study to observe the Threshold Suspend (TS) feature with a sensor-augmented insulin pump in patients 16 and older with insulin-requiring diabetes. The study will measure the change in HbA1c from baseline over a period of one year while subjects are wearing the Medtronic MiniMed® 530G insulin pump.

Investigational centers (50 sites) will be selected across the United States. Up to 1,200 subjects will be enrolled so that there will be 1000 subjects who are eligible to participate in the study for hypothesis test. The 1000 subject sample size was calculated based on an overall consideration of the primary hypothesis, drop-out rate (20%), compliant rate (65%), and ability to detect serious adverse events (14.5%).

The primary endpoint is the overall mean change in HbA1c from baseline to 12-month follow-up. The secondary endpoint is the mean change in HbA1c from baseline to end of study for each individual HbA1c cohort (i.e., less than 7.0%, 7.0-9.0%, greater than 9.0%). Safety endpoints include Serious Adverse Events, Unanticipated Device Effects, Incidence of Severe Hypoglycemia, Incidence of Severe Hyperglycemia, and Incidence of Diabetic Ketoacidosis. Adverse Events will

be stratified by age, ethnicity, baseline BMI, gender, duration of diabetes, hypoglycemia awareness, frequency, and average duration of hypoglycemic event (based on two weeks prior to the adverse event). Descriptive summary statistics will be provided for HbA1c change, Hypo/Hyperglycemia Events, TS Metrics, Device Utilization, CGM Metrics, Device Performance, and Effectiveness of educational materials. Descriptive subgroup analysis of HbA1c data will be performed on demographic cohorts.

Each patient will be followed-up in 5 visits in the 12-month period, every 90 days from the enrollment.

For the primary analysis, a random effect model will be used to produce the estimate and confidence interval of the overall mean change in HbA1c while accounting for inter-site variability. Sensitivity analysis will be performed on the intent to treat population with multiple imputations. The primary endpoint will also be summarized (descriptive statistics) and stratified by: Investigational Site, Age, Race, Ethnicity, Baseline BMI according to WHO criteria, Gender, Diabetes Classification, Duration of Diabetes, and Hypoglycemic awareness at Baseline Questionnaire. All adverse events will be summarized by: Insulin Pump Infusion set, Insulin administration and pump use, Sensor Use, Severe Hypoglycemia, Severe Hyperglycemia, Diabetic Ketoacidosis, Adverse Device Event, Serious Adverse Event and Unanticipated Adverse Device Effect. Adverse Events by Investigator will also be provided. No formal statistical analysis will be carried out. In addition, data will be collected for a descriptive summary of device disposition, adverse events, device performance, and user acceptance.

Please be advised that the results from these studies should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement.

FDA would like to remind you that you are asked to submit separate PAS Progress Reports every four months during the first year, every six month during the second year of the study, and annually thereafter. The reports should clearly be identified as Post-Approval Study Report. Two copies for each study, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

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" (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 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 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 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 approved labeling in final printed form. Final printed 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 printed labeling is identical to the labeling approved in draft form. If the final printed 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.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Stayce E. Beck, Ph.D., M.P.H. at 301-796-6514.

Sincerely yours,

Alberto Gutierrez -S

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