On September 19, 2013 Medtronic received a warning letter from the U.S. Food and Drug Administration. We have been working closely with the FDA to determine the appropriate steps to address the warning letter and the FDA has granted approval for the MiniMed 530G.

This is a letter sent to Medtronic; no action is presently required by patients or physicians related to this letter.

Please know that we take these findings very seriously. Medtronic has been working very closely with the FDA, have already addressed many of the observations noted in the warning letter, and we are committed to resolving the remaining observations as quickly as possible. We want to ensure you that we are committed to providing safe and effective products for people with diabetes.

Q1. What is the warning letter about?
   A. The warning letter outlines observations identified in a recent facility audit and are related to the following six categories: corrective and preventive action, complaint handling processes, process validation, process monitoring, design control and general good manufacturing practices. We remain committed to providing quality products to our customers and to continuously improving our systems and processes.

Q2. Are Medtronic customers at increased risk because of the issues raised in the warning letter?
   A. The observations address areas of needed improvement in our Quality Management system and relate to documentation and quality processes. There are no specific patient risk issues that require new communication to patients, nor is there any action presently required of any patients or physicians related to products as a result of this letter. We are confident in the reliability of our Paradigm insulin pump platform and its ability to deliver safe and effective therapy for those who need it.

Q3. What steps have you taken and will you take to resolve the outstanding issues? What is the expected timeframe for closing the warning letter?
   A. We are working swiftly and comprehensively to address the required actions outlined in the warning letter. The warning letter acknowledges the extensive work we have already completed to address many of the observations noted by the FDA. While we are doing everything we can to make sure the FDA’s concerns are addressed as quickly as possible, it’s difficult to provide a specific timeline for closing the warning letter. The timeline for closing the warning letter also depends on the FDA’s assessment of our actions, including the potential for a follow-up inspection.

Q4. Will the company have to make any modifications to current or future products as a result of this warning letter?
   A. Medtronic makes necessary and ongoing modifications and improvements to current products as part of our Corrective and Preventive Action (CAPA) process. Several open CAPA items were referenced in the warning letter. As part of our standard quality procedures, Medtronic will complete the CAPA process for all open CAPA items, which may result in modifications or improvements to existing products. Maintaining quality of our products is the most important thing we do at Medtronic.