Medtronic, Inc.
8200 Coral Sea St NE
Mounds View, MN 55112

February 19, 2009

Louis Jacques, MD
Director, Division of Items and Devices
Centers for Medicare and Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
7500 Security Blvd.
Mail Stop C1-09-06
Baltimore, MD 21244

Re: Formal Request for Reconsideration of the National Coverage Determination (NCD) for Magnetic Resonance Imaging (MRI) (CAG-00399R) to revise the Contraindication for Cardiac Pacemakers (Section 220.2 of the Medicare NCD Manual)

Dear Dr. Jacques:

Thank you for opening the NCD for Magnetic Resonance Imaging (MRI). On behalf of Medtronic, Inc, we formally request a revision of the language on contraindications articulated in the current policy. Specifically, we ask that the reference to cardiac pacemakers be revised to include coverage for devices that have been designed, tested and FDA labeled, for use in the MRI environment.

As you know, cardiac pacemakers are one of two devices specifically contraindicated for MRI scanning in the original policy, which was developed in 1994. Since that time, there have been numerous articles and a national guideline supporting the careful use of MRI with pacemaker patients. We believe that this is sufficient evidence to modify the NCD, at this time (citations attached).

Other authors in the literature suggest that only specifically designed pacemakers should be considered MRI compatible. We have already addressed that concern. A cardiac pacemaker system has been developed that allows patients to safely undergo MRI scans. Medtronic obtained CE Mark for its system in September 2008 and has begun marketing it in Europe. In the US it is considered an investigational product, currently undergoing clinical study, and Medtronic is actively pursuing FDA approval[1].

While we have addressed this additional concern through product innovation, we do not believe that, given the existing safety literature, a change should be delayed until FDA labeling occurs.

[1]This Medtronic pacemaker system is currently being investigated in the EMRI SureScan™ Clinical Study, (ClinicalTrials.gov identifier NCT00433654)

Therefore, we respectfully request the language in the NCD be revised to say:

> "The MRI is not covered when the following patient-specific contraindications are present. It is not covered for patients with *devices that have not been approved or cleared by the FDA for use in the MRI environment"*...

at this time.

Thank you for your consideration of this request. If you have any questions or require additional information, please feel free to contact me or Franceen Horin, Senior Reimbursement Manager at 763-526-2938 or franceen.horin@medtronic.com.

Sincerely,

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Attachment

MRI Language Modification Documentation

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MRI Language Modification Documentation

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