1) SAR exhibit states:
"The resultant changes did not affect the RF power output of the unit as determined from measurement of the radiated field in the torso simulator required by the FCC." Radiated power test does not appear to use a set-up in accordance with 95.639(f)(2)(i) - in that case please explain how analysis in RF exposure exhibit is applicable, or revise accordingly. Explanation should be in terms of technical parameters, not based on SAR magnitude relative to limit.

Response:
The statement in the SAR exhibit was meant to only reinforce the conclusions in the SAR report FDTD analysis that the implant continues to comply with the Commission's RF exposure guidelines. Since the radiated test data taken using the same basic setup and tissue characteristic material (as explained later the locating shelf was not centered) produced very nearly the same measured EIRP, it is reasonable to conclude that the SAR levels should be nearly the same as previously calculated. We apologize if the statement caused any confusion.

2) Graphics in SAR exhibit appear to be from "Microwave Studio" software package, which is understood to use a so-called finite-integration time-domain (FITD) solution method. Please explain how this fulfils FCC rules requirement for finite-difference time-domain (FDTD) modeling. Be sure to include (summary) details about how FITD is same as FDTD, if it is.

Response:
The SAR graphs were not generated by Microwave Studio. They were generated by Remcom xfdtd (ver. 6.2), which is an implementation of the Finite-Difference Time-Domain (FDTD) method.

3) Please address info about SAR modeling as specified in OET 65 Suppl C Appdx B sect. III.

Responses to questions 1 to 12 in Sect III are listed below:
1. Computational resources:

Remcom xfdtd (ver. 6.2), which is the latest implementation of the Finite-Difference Time-Domain (FDTD) method running on a high end Windows based computer. The computational tool used for the FDTD analysis is the XFDTD Remcom software specified above. An earlier version of the Remcom software implementing the Visible Man Model was used by Medtronic to show RF exposure compliance with the FCC Rules. For the Class II change submitted in this application, it was the opinion of the experts at Medtronic that a reduced size model using a smaller mesh size in order to correctly model the antenna structure should be used. To insure the integrity of the analysis the antenna surfaces were maintained at 4cm distance from the wall in the transverse plane and 3 cm from the wall in the normal plane. The smallest distance between the can and the wall is 2cm. For this analysis a 1 mm mesh was used to

correctly model the antenna with a reduced size biomodel in order to reduce the computational time from days to several hours.

2. FDTD algorithm implementation and validation.

The FDTD analysis method is a solution of Maxwell's equations that is implemented by Remcom. Their implementation has been accepted in the industry and by the FCC for implant related applications.

3. Parameters

a. Computational parameters:
Cell size: 1 mm,
Domain size: 4 cm x 4 cm x 3 cm
Time step size: 9.629 10e-13 secs
Tissue separation from boundary (PEC): 0 cm

b. Computational efficiency vs. model accuracy:
The cell size was selected to allow for accurate physical modeling of the antenna although past experience indicates that a simpler model of the antenna would have provided similar results. The simulation was performed in muscle tissue only as a way to provide a conservative result. Muscle tissue is lossier than many other tissues.

4. Phantom model implementation and validation

a. A phantom model in the typical context of SAR measurements was not used in this analysis. The model that was used is the form factor for actual implant consisting of a titanium can with a plastic header for lead attachment that houses the antenna also. Dielectric parameters of the model were selected and validated in a variety of ways. The dielectric properties for tissue are a built function of Remcom software program. The input dielectric constant of the plastic header was 3.7 and the conductivity of all metallic structures such as antenna and can were for an ideal conductor.

b. A review of tissue dielectric properties indicates that at 403.5 MHz, muscle provides the most loss and therefore would absorb the most radio energy. Muscle tissue was chosen for the simulation to provide the most conservative results.

c. Procedures to verify that our phantom model has been correctly constructed.
The model used was an actual Medtronic implant. Dimensions used to construct the model are accurate to within 0.5mm including antenna location and placement within the implant header.

5. Tissue dielectric parameters

The tissue dielectric parameters are built into this version of the Remcom XFDTD modeling program. They are specific to the frequency and tissue type that are input parameters. Normal installation of the implant is in muscle tissue in the upper chest. The highest RF exposure levels are in close proximity to the antenna and case of the implant. The maximum levels are associated with muscle as the appropriate tissue material for the FDTD analysis.

6. Transmitter model implementation and validation.

The transmitter was modeled as a metallic can, plastic header and loop antenna contained within the plastic header. Descriptions and illustrations of the model are shown on page 2 of the submitted modeling report showing the comparison between the models and the actual devices. Page 3 shows the modeling results of the SAR distribution at 403.5 MHz. It is not expected that results would vary over the MICS band. Transmitter output power that is an input parameter to the software was measured by direct connection to a calibrated HP 8595E spectrum analyzer.

7. Test device positioning.

The modeled implant device with the surrounding biomodel of tissue material is basically equivalent to the actual installation within a human torso. A 3D view of the modeled device is shown on page 4 of the SAR report.

8. Steady state termination procedures

Steady state conditions were obtained when the field levels reached low relative unchanging levels. This was done by observing one point in the near field to see if the fields stabilized.

9.Computing peak SAR from field components
Functionally addressed by the Remcom software via a built-in SAR post-processor.

10. One-gram averaged SAR procedures
Functionally addressed by the Remcom software via a built-in SAR post-processor.

11. Total computational uncertainty

The results were consistent with expected levels that are well below the compliance limits. Because the implant device radiates less than 1.6 milli-Watts, it is impossible for any one gram of body tissue to absorb more than the imposed regulatory limit. Therefore, computational uncertainty was not specifically addressed. Factors that would be important for determining the uncertainty would be the transmit power measurement and the geometry of the model and the material parameters such as conductivity and dielectric constant. Due to the relatively low frequency of the MICS band, the simulation results are not strongly influenced by the shape of the implant. However, the implant model was accurate to within 0.5mm to optimize fidelity of the model.

12. Test results for determining compliance

a. See report for illustrations showing SAR distributions.
b. Each CRMC implant device is factory tuned to output the essentially the same power.
c. Average SAR functionally is addressed by the Remcom software via a built-in SAR post-processor.

4) Please address the following in accordance to Section 95.639(f)(2)(i):

Was the human torso simulator for testing medical implant transmitters consists of a cylindrical Plexiglas container with a size of 30 cm by 76 cm with a sidewall thickness of 0.635 cm. Was the Plexiglas container completely filled with a material that is sufficiently fluidic that it will flow around the implant without any voids. Was the dielectric and conductivity properties of this material must match the dielectric and conductivity properties of human muscle tissue at 403.5 MHz. All emissions measurements will be made using the above specification at a nominal temperature of 20-25°C. Mounting grid for the implant inside the container must be provided that permits the radiating element or elements of the implant to be positioned vertically and horizontally. The implant must be mounted 6 cm from the sidewall and centered vertically within the container. The above fixture shall be placed on a turntable such that the implant transmitter will be located at a nominal 1.5- meter height above ground and at a 3-meter distance from the measurement antenna. Radiated emissions measurements shall then be performed to insure compliance with the applicable technical specifications.

Response:

The torso simulator dimensions used for the radiated testing are as follows: The wall thickness is .25 in or .635 cm. The height is 30 in or 76.2 cm. The outer diameter is 12 in or 30.48 cm. The inner diameter is 11.5 in or 29.2 cm. We confirm the dielectric and conductivity properties of the human muscle tissue were 0.94 S/m and 57.0 for dielectric constant for a frequency of 403.5 MHz and that it was sufficiently fluidic to flow around the implant. Please refer to paragraph 4.6 of the submitted test report. All measurements were made using the above container and tissue material with a nominal temperature between 20^{o}C and 25^{o}C. The mounting grid for the implant within the container permitted the implant to be held in a horizontal plane and in a vertical plane with a spacing to the sidewall of the simulator container of 6 cm. The shelf used to support the implant was not centered as specified due to use of the torso simulator for SAR measurements for implants at other frequencies. The location of the shelf for these SAR measurements was coordinated with FCC personnel for the SAR measurements. Unfortunately, the shelf was permanently attached with a resin material preventing relocation of the shelf to the center. However, the tissue substitute material covered the implant at a minimum depth of 14 to 19 cm. It is reasonable to assume this difference would not cause any errors in the measurement results. The height of the implant above

ground was set a 1.5 meters and the separation distance from the measurement antenna of 3 meters. All final measurements were taken using the above setup.