DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

MEMORANDUM

SUMMARY OF:

P080006/S006 Attain Ability Model 4196, 4296, and 4396 Left Ventricular Leads

---

BACKGROUND

This PMA supplement was submitted to gain approval for the following:

1. To use the Monolithic Controlled Release Device (MCRD) component-level analytical testing, only, for release of the Medtronic Attain Ability Model 4196 left ventricular lead rather than both finished lead and component-level testing;

2. To switch to a 50 rpm paddle rotor speed instead of using a 100 rpm and a 50 rpm paddle speed for all elution testing going forward;

3. To close a condition of approval for the Model 4196 lead under P080006 requesting test results and analysis of in vitro drug elution testing using a 100 rpm and a 50 rpm paddle speed for both the ring and tip electrodes of the finished lead product.

The second and third items above were approved in a separate submission (P080006/S019), so the only remaining request in the subject submission is that for use of (b) (4) (b) (4). In addition, two other lead models in the 4x96 lead family received approval after submission of P080006/S006- Model 4296 was approved 1 April 2011 under P080006/S002 and Model 4396 was approved 31 March 2011 under P080006/S004. Therefore, the firm would like to extend its request for (b) (4) to these models as well.

Several rounds of review including (b) (4) were conducted to address the initial concerns with the file:

After review of the **original submission**, a Major Deficiency letter was sent (20 May 2010) regarding the potential (and untested) effect of sterilization on several CMC tests and concerns about the use of a conversion factor for elution testing of the tip MCRD (component only) vs finished product. These concerns were discussed with the firm in at a 17 June 2010 teleconference.

Amendment A001 regarded extension of the due date extension in order to provide complete responses to FDA deficiency questions.

In **Amendment A002**, Medtronic responded to the FDA deficiency letter dated 20 May 2010. The sterilization concern was addressed with further testing, but review of the (b) (4) (b) (4) noted remaining issues. The use of a model with various correction factors to account for the (b) (4) still a concern. A (b) (4) was sent (b) (4). A teleconference was held 26 July 2011 to discuss FDA's letter.

(b) (4)

Amendment A003 regarded extension of the due date extension in order to provide complete responses to FDA deficiency questions.

(b) (4)

In **Amendment A004**, Medtronic responded to the (b) (4)
(b) (4) .

INDICATIONS FOR USE

The indications for use, contraindications, warnings and precautions for the Attain Ability lead models have not changed:

> "The Medtronic Attain Ability Model 4196 lead is intended for chronic pacing and sensing in the left ventricle via the cardiac vein when used in conjunction with a compatible Medtronic Cardiac Resynchronization Therapy (CRT)."

DEVICE DESCRIPTION AND CHANGE DESCRIPTION

The Attain Ability Model 4196 lead is a left ventricular, 4 Fr, transvenous, steroid eluting, dual electrode, (b) (4) e outer insulated, (b) (4)), cardiac vein lead with an IS-1 connector. A compound curve at the distal end provides fixation within the cardiac vein. The bipolar lead can be implanted using either a guidewire or a stylet. Its two electrodes are coated with (b) (4)). The (b) (4) and is contained in two Monolithic Controlled Release Devices (MCRDs)- one at each electrode. The target dose of the proximal ring MCRD is (b) (4)
(b) (4) . The (b) (4) seal at the very distal end of the lead allows guidewire passage while minimizing blood ingress into the lead lumen.

Models 4296 and 4396 differ from the Model 4196 in the following ways:

- The lead body tubing for Model 4296 is larger up to the proximal end of the ring electrode resulting in a larger diameter of 5.3 Fr.
- The fixation method of Model 4396 relies on a (b) (4) of (b) (4) .

MCRD components and configuration are identical for all three lead models.

BENCH TESTING

(b) (4)

(b) (4)

[redacted]

OTHER REVIEW ELEMENTS

The following areas are not relevant for the subject review:

- Clinical
- Animal Testing
- EMC/EMI
- Biocompatibility
- Manufacturing
- Human Factors
- Packaging, sterilization, shelf-life
- Labeling
- Marketing

CONCLUSION/ RECOMMENDATION

Based on the additional information provided in throughout the review and, finally, in **Amendment A004**, the remaining concerns are now resolved. The sponsor has provided sufficient evidence to

demonstrate that component level testing can be used in lieu of finished product testing for the following evaluations:

- Assay, Related Substances, and Elution for the ring MCRD
- Assay and Related Substances for the tip MCRD

I recommend that the sponsor receive an **APPROVAL** letter.