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ATTACHMENT C

AUG 10 1987

Summary of Equivalence Data for the Modified Medtronic®  
Classix™ Models 8436/8437/8438 Pulse Generators  
Summary of Equivalence

I. General Information

Device Generic Name: Implantable Pacemaker Pulse  
Generator  
Device Trade Name: Classix™ Models 8436/8437/8438  
Pulse Generators  
Applicant's Name and Address:  
Medtronic, Inc.  
7000 Central Avenue N.E.  
Minneapolis, MN 55432  
510(k) Number:

II. Description of the Diseases and Conditions for Which  
the Modified Classix™ Pulse Generators are Indicated

The indications for the modified Classix pulse genera-  
tors are identical to the indications for the commer-  
cially available Classix pulse generators. General  
indications for permanent ventricular pacing include  
the following:

- Long-term therapeutic control of heart rate in patients with second degree (usually Mobitz Type II) and third degree A-V block
- Sick sinus syndrome
- Certain drug-resistant tachycardias
- Complete A-V block and certain bifascicular blocks following acute myocardial infarction
- Intractable congestive heart failure, bradycardia angina, and cerebral or renal insufficiencies benefited by pacing
- Atrial fibrillation with slow ventricular response

General indications for permanent atrial pacing include the following:

- Sinus arrest
- Sinus bradycardia
- Sick sinus syndrome (bradycardia-tachycardia syndrome)

Noncompetitive pacing is the indicated pacing mode in the presence (or likelihood) or competitive rhythms.

III. Device Description

A discussion of equivalence between the current Classix and modified Classix pulse generators is provided below.

Design

The modified Classix pulse generators are identical to the current Classix pulse generators except that a trim resistor on the hybrid circuit is trimmed such that the

modified devices activate the Elective Replacement Indicator (ERI) at a battery voltage of 2.55V whereas the current devices activate the ERI at a battery voltage of 2.15V. Also, three capacitors were added to the hybrid circuit to ensure proper ERI operation at the higher ERI voltage (2.55V). This modification is being made because it has been determined that the current version of Classix pulse generators may have as little as one month of pacing life between the ERI (2.15V) and end-of-life (EOL) (1.8V).

In addition, the modified version of Classix uses a battery with a 50:1 iodine to polyvinylpyridine cathode weight ratio, whereas the current version of Classix uses a battery with a 20:1 ratio. This change is being made so that the Classix battery will use the same battery technology as most other Medtronic pacemaker batteries.

#### Materials

The materials which contact body tissue in both the current Classix and the modified Classix devices are identical.

#### Performance

Modifying the hybrid circuit to increase the voltage level at which the ERI is activated has the following effect on device performance. The current devices have approximately one month of pacing life between the ERI (2.15V) and EOL (1.8V) at 70ppm, 0.5ms, and 5.0V. The modified devices will have approximately four months of pacing life between the ERI (2.55V) and EOL (1.8V) at 70ppm, 0.5ms, and 5.0V.

The modified battery will affect device performance by increasing the deliverable energy, and therefore the device longevity, by approximately 10%.

The engineering series number (part of the radiopaque code) has been changed to allow the modified Classix pulse generators to be uniquely identified following implantation. This as well as the differences in device function, is described in the revised Classix technical manual (Attachment A).

#### IV. Alternatives

While surgery or drug therapy may be alternatives to cardiac pacing in certain instances, cardiac pacing is often the standard treatment for the indications described in Section II above. Other commercially available single chamber pulse generators provide alternatives to the Classix pulse generators.

#### V. Potential Adverse Effects

Potential adverse effects associated with all pacemaker

systems include: loss of normal pacemaker function due to battery failure or other component failure; inability to reprogram a pacemaker pulse generator because of programmer failure; interruption of desired pacemaker function due to electromagnetic interference; infection; erosion of the pulse generator through the skin; undesired muscle or nerve stimulation; and inadequate sensing or pacing.

#### VI. Summary of Studies

Qualification testing of the battery was performed to verify its suitability for implantable use. Specific testing was also performed to determine the time between the elective replacement indicator (ERI) and device end-of-life (EOL).

Environmental testing and electromagnetic compatibility (EMC) testing were also performed to verify that the battery and circuit modifications do not adversely affect device performance.

##### A. Battery Testing

Accelerated testing, application testing, and environmental testing were performed to verify the projected deliverable capacity of the battery.

One hundred twenty-eight batteries were discharged at various accelerated current drains. The 112 batteries that have completed this testing have delivered an average of 1.06 Ah. These results support the battery capacity stated in the technical manual.

Application testing is being performed with sixteen batteries discharging at  $16\mu\text{A}$ . These batteries have been on test for 25 months and are exhibiting high reliability. These cells have delivered approximately 300mAh to date and are expected to meet the deliverable capacity stated in the technical manual.

Environmental testing was performed to verify that environmental conditions did not significantly affect the battery performance. Sixteen batteries were exposed to combinations of shock and vibration, low temperature storage, and high temperature storage. The results of this testing indicate that environmental conditions do not significantly affect battery performance.

Testing was also performed to determine the time between the ERI (2.55V) and EOL (1.8V). Sixty-four cells were discharged in real time from 2.55V to 1.8V at  $22\mu\text{A}$ . These data were then modeled to

determine the time between the ERI (2.55V) and EOL (1.8V) at 29 $\mu$ A, which is the device current drain at 5.0V, 0.5ms, and 70ppm with the magnet applied. At 5.0V, .05ms, and 70ppm with the magnet applied, the time between the ERI (2.55V) and EOL (1.8V) is projected to be a mean of 5.6 months. At these same settings, 95% of the population is projected to last at least 4.3 months with 95% confidence. These results support the information supplied in the technical manual regarding device performance near EOL.

B. Environmental Testing

To assure that the Model 8436/8437/8438 pulse generators would perform adequately in typical operating, shipping, and handling environments, environmental stress testing was performed. Eleven (11) functional Model 8436 and eleven (11) functional Model 8437 pulse generators were tested. The Model 8438 is identical to the Model 8436 except for the connector configuration, therefore, testing performed on the Model 8436 is applicable to both. These tests consisted of temperature cycle (-18°C to +55°C for 6 hours each), mechanical vibration (5Hz to 500Hz at 2.5g), and mechanical shock (600g/effective free fall height = 18"). The devices were electrically checked before and after environmental testing on automatic test equipment. There was no visible physical damage resulting from the tests, and no significant shifts in output parameters: pulse width, amplitude, sensitivity, and lower rate interval.

The pass/fail criteria are:

- 1) The parameters must remain within specification.
- 2) No appreciable shifts in electrical parameters.
- 3) No physical degradation resulting from the environmental stress test.

The output parameter limits monitored are as follows:

pulse width - 475 to 525 $\mu$ s  
 sensitivity - 2.20 to 2.90mV  
 amplitude - 4.85V min.  
 lower rate interval - 857  $\pm$  3ms

All of the pulse generators satisfied the above criteria and therefore passed the tests.

C. Electromagnetic Compatibility (EMC) Testing

EMC testing of the Models 8436/8437 pulse generators was accomplished to determine their performance under the influence of various electromagnetic

interference conditions. Three (3) Model 8436 and three (3) Model 8437 pulse generators were utilized for the testing. The Model 8438 is identical to the Model 8436 except for the connector configuration, therefore, testing performed on the Model 8436 is applicable to both. The devices were tested per AAMI Pacemaker Standard (¶3.4.8). The acceptance criteria as defined in ¶3.4.8 are that the pulse generator with lead attached shall not exhibit any of the following operating modes:

- 1) rate exceeding 150ppm
- 2) rate below 50ppm
- 3) a change of pulse amplitude or duration of more than 20%
- 4) the pulse generator pulse rate duration and amplitude shall be unchanged within two seconds of termination of the energy source

Electromagnetic compatibility testing consisted of exposure to radiated energy at 450MHz of 400 volts per meter and conducted energy at 50, 60, and 600Hz of 100mV RMS per AAMI Pacemaker Standard, ¶4.1.8.1 and ¶4.1.8.2, respectively.

Electrical testing before, during, and after EMC testing indicated that the above criteria had been met and that there was no significant difference in performance to that of previously tested Classix devices.

#### VII. Conclusions

The in vitro results demonstrate that the modification to the Classix pulse generators has been adequately tested to verify the reliability of the changes made.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

AUG 10 1987

Food and Drug Administration  
8757 Georgia Avenue  
Silver Spring MD 20910

Mr. Timothy D. Samser  
Sr. Product Regulation Manager  
Pacing Business Unit  
Medtronic, Inc.  
7000 Central Avenue, N.E.  
Minneapolis, MN 55432

Re: K871866  
Trade Name: Medtronic Classix Models  
8436/8437/8438  
Regulatory Class: 74-III  
Dated: May 5, 1987  
Received: May 13, 1987

Dear Mr. Samser

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Pre-market Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Abhijit Acharya, Ph.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

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