Medical Center

3200 Vine Street
Cincinnati OH 45220

Veterans Administration

In Reply Refer To: 539/115

United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Gentlemen:

The following response is pursuant to renewal of the Nuclear Powered Pacemaker License. Our NRC license number is SNM-1735 and our program code number is 22160.

(a) License Number: SNM-1735
Expiration Date: May 31, 1987
Program Code: 22160

(b) Veterans Administration Medical Center
3200 Vine Street
Cincinnati, Ohio 45220

(c) Two pacemakers have been authorized, NRC number SNM-1735 reference number 070-02580 (not to exceed 210 milligrams each). Both are Medtronic Model 9000 Nuclear Powered Pacemakers. One remains implanted; the other was removed and returned to Medtronics on 9-18-86. (See enclosed sheet)

(d) We are requesting authorization to follow the patients with implanted pacemakers, not for implantation or reimplantation.

(e) Please add the following physicians who are involved in the pacemaker program:

1. Jon Rogers, M.D., Staff Cardiologist
2. Yitzchak Hermoni, M.D., Staff Cardiologist
(See enclosed information)

Sincerely,

Donald L. Ziegenhorn

DONALD L. ZIEGENHORN
Medical Center Director

Enclosures: 2

5/6/87

JAMES W. FLETCHER, M.D.
Director, Nuclear Medicine Service (115)
Veterans Administration
Washington, DC 20420

Medtronic

PRODUCT EVALUATION REPORT

Instructions: Use this form to report your experience with a Medtronic product or when returning a device for analysis. This information is necessary and will expedite processing for warranty consideration.

Please indicate model and serial numbers of the device(s) involved: Pulse Generator		Lead(s) →	Model No.:	Serial No.:
Model No.: 9000	Serial No.: 5R00217		Model No.:	Serial No.:

GENERAL INFORMATION

Physician: M. BRANCO		Hospital: V-A.		
Patient Name:		Street Address:		
Date of Implant:	Date of Explant: 9/15/86	City: Lexington	State: KY	Zip:

CLINICAL INFORMATION

NOTE: Please include all pertinent medical records including EKG's.

Reported Experience:

- ☐ Elective Replacement
- ☐ Patient Expired
- ☐ Infection
- ☐ Erosion
- ☐ Other (please explain):
- ☐ Battery Depletion
- ☐ Rate Change ____ bpm to ____ bpm
- ☐ No Output
- ☐ Visual Irregularity:
- ☑ Noncapture
- ☐ Oversensing
- ☐ Undersensing
- ☐ Programming Difficulty
- ☐ Positioning Difficulty
- ☐ High Threshold Readings
- ☐ Fractured Lead
- ☐ Stylet Difficulty

Reported experience was observed:	☐ Continuously ☑ Intermittently	Pacing Mode while implanted:	☐ DDD ☑ VVI ☐ DVI ☐

Programmed Parameters While Implanted:

Pulse magnitude: _____ (volts) Pulse Width: _____ Pulse Interval (Rate): _____

Sensitivity: _____ Refractory: _____ A-V Interval: _____

Lead Status: ☐ Reused ☐ Repaired ☐ Unipolarized ☐ Repositioned ☑ Replaced ☐ Capped

REPLACEMENT INFORMATION

If replaced, indicate replacement device(s): Pulse Generator: HJ202725H	Lead(s) →	Model No.: 6962-58	Serial No.: UB00763 10V
Model No.: 8422	Serial No.:	Model No.:	Serial No.:

FOLLOW-UP INFORMATION

Please indicate the name, address and phone number of the person to receive follow-up information:

Name: M. BRANCO.		Area Code	Phone
Address:			
City: LEXINGTON	State: KY.	Zip:	

If you have a complaint, please specify:

Evaluation Report completed by: D. ZEIGLER Date: 9/15/86

Medtronic

PRODUCT EVALUATION REPORT

Instructions: Use this form to report your experience with a Medtronic product or when returning a device for analysis. This information is necessary and will expedite processing for warranty consideration.

Please indicate model and serial numbers of the device(s) involved:

Pulse Generator Model No.:	Pulse Generator Serial No.:	Lead(s) Model No.:	Lead(s) Serial No.:
9000	5K00217		

GENERAL INFORMATION

Physician: M. BRANCO

Patient Name:

Date of Implant:

Date of Explant: 9/15/86

Hospital: V.A.

Street Address:

City: LEXINGTON State: KY Zip:

CLINICAL INFORMATION

NOTE: Please include all pertinent medical records including EKG's.

Reported Experience:

- ☐ Elective Replacement
- ☐ Patient Expired
- ☐ Infection
- ☐ Erosion
- ☐ Other (please explain):
- ☐ Battery Depletion
- ☐ Rate Change ____ bpm to ____ bpm
- ☐ No Output
- ☐ Visual Irregularity:
- ☑ Noncapture
- ☐ Oversensing
- ☐ Undersensing
- ☐ Programming Difficulty
- ☐ Positioning Difficulty
- ☐ High Threshold Readings
- ☐ Fractured Lead
- ☐ Stylet Difficulty

Reported experience was observed: ☐ Continuously ☑ Intermittently

Pacing Mode while implanted: ☐ DDD ☑ VVI ☐ DVI ☐ ____

Programmed Parameters While Implanted:

Pulse magnitude: _____ (volts) Pulse Width: _____ Pulse Interval (Rate): _____

Sensitivity: _____ Refractory: _____ A-V Interval: _____

Lead Status: ☐ Reused ☐ Repaired ☐ Unipolarized ☐ Repositioned ☑ Replaced ☐ Capped

REPLACEMENT INFORMATION

If replaced, indicate replacement device(s):

Pulse Generator Model No.	Pulse Generator Serial No.	Lead(s) Model No.:	Lead(s) Serial No.:
X422	HJ202725H	6962-58	UR0076310V

FOLLOW-UP INFORMATION

Please indicate the name, address and phone number of the person to receive follow-up information.

Name: M. BRANCO. Area Code: Phone:

Address:

City: LEXINGTON State: KY. Zip:

If you have a complaint, please specify:

Evaluation report completed by: [signature] Date: 11/14

Medical Center

3200 Vine Street
Cincinnati OH 45220

Veterans Administration

April 29, 1987

In Reply Refer To:

I have read the Nuclear Pacemaker Protocol approved by the Nuclear Regulatory Committee, and agree to follow this protocol concerning this patient.

4/27/87.

Jon Rogers, M.D. Date

1. Name	Jon M. Rogers, M.D.
2. Address	Cincinnati V.A. Medical Center Division of Cardiology 3200 Vine Street Cincinnati, Ohio 45220
3. Telephone number	861-3100 Extension 5072 (pager number 287)
4. License	Ohio 043831
5. Board	1) American Board of Internal Medicine (Specialty-Internal Medicine) 2) American Board of Internal Medicine (Subspecialty-Cardiovascular Disease)
6. Position at V.A.	Staff Cardiologist
7. Previous Experience with pacemakers	Pacemaker Clinic at the Cincinnati VAMC July, 1984 to present

Medical Center

3200 Vine Street
Cincinnati OH 45220

Veterans Administration

April 21, 1987

In Reply Refer To:

I have read the Nuclear Pacemaker Protocol approved by the Nuclear Regulatory Committee, and agree to follow this protocol concerning this patient.

Y Hermoni MD 4/27/87

Yitzchak Hermoni, M.D. Date

1. Name	Yitzchak Hermoni
2. Office Address	Cincinnati V.A. Medical Center Division of Cardiology 3200 Vine Street Cincinnati, Ohio 45220
3. Telephone Number	861-3100 Extension 5072 (pager number 273)
4. License	OHIO 49869 Maryland D28448
5. Board	1) American Board of Internal Medicine (Specialty- Internal Medicine) 2) American Board of Internal Medicine (Subspecialty- cardiovascular disease)
6. Position at V.A.	Staff Cardiologist
7. Previous Experience with pacemakers	Pacemaker Clinic at the Cincinnati VAMC July, 1980 to present

CONTROL NO. 83527