MEDTRONIC IMPLANTABLE DEMAND

ISOTOPIC PULSE GENERATOR

LAURENS-ALCATEL MODEL 9000

SUMMARY OF CLINICAL EVALUATION STUDY

Submitted to the

UNITED STATES NUCLEAR
REGULATORY COMMISSION

October, 1996

INTRODUCTION

Six hundred sixty-two (662) implants of Medtronic Model 9000 isotopic pulse generators, or nuclear-powered pacemakers have been recorded in the United States since 1972, according to reports submitted to Medtronic. Physicians and hospitals licensed to implant these devices have done so under a clinical investigation plan approved by the United States Nuclear Regulatory Commission.

The Model 9000 performance has been documented in twenty four(24) previous evaluation reports. Results conclusively demonstrated that the Model 9000 is at least as reliable as chemically-powered units. However, improved longevity of chemically-powered units, primarily lithium, have considerably decreased the need for a nuclear-powered unit. Therefore, Medtronic is no longer selling the Model 9000 pulse generator with a nuclear power source.

This summary documents the status of the Model 9000 pulse generator as of October, 1996, and updates the previous summary of October, 1995. It also clearly demonstrates that complete and continuous accountability for all nuclear devices will not be maintained.

Attachment

I. Current status of the Model 9000 pulse generator.
II. Explants not previously reported.
III. Review of failures.
IV. Statement of Model 9000 accountability.

Previous Reports

Medtronic, Inc., Status Report No. 1 of the Clinical study of the Medtronic Laurens-Alcatel Model 9000 Isotopic Pulse Generator. Minneapolis, Unpublished Manuscript, November 20, 1973.

Ibid., Status Report No. 2, June 28, 1974
Ibid., Status Report No. 3, November 24, 1974
Ibid., Status Report No. 4, May 24, 1975
Ibid., Status Report No. 5, November 24, 1975
Ibid., Status Report No. 6, May 24, 1976

Medtronic Implantable Demand Isotopic Pulse Generator Laurens-Alcatel Model 9000, Summary of Clinical Evaluation Study. Minneapolis, Unpublished Manuscript, November 24, 1976

Ibid., Summary No. 2, May 25, 1977
Ibid., Summary No. 3, May 26, 1978
Ibid., Summary No. 4, May 26, 1979
Ibid., Summary No. 5, December 15, 1980
Ibid., Summary No. 6, May 26, 1981
Ibid., Summary No. 7, June 25, 1982
Ibid., Summary No. 8, May, 1983
Ibid., Summary No. 9, September, 1984
Ibid., Summary No. 10, October, 1987
Ibid., Summary No. 11, October, 1988
Ibid., Summary No. 12, October, 1989
Ibid., Summary No. 13, October, 1990
Ibid., Summary No. 14, October, 1991
Ibid., Summary No. 15, October, 1992
Ibid., Summary No. 16, October, 1993
Ibid., Summary No. 17, October, 1994
Ibid., Summary No. 18, October, 1995

ATTACHMENT I

CURRENT STATUS OF THE MODEL 9000 PULSE GENERATOR

I. Implant Data

A.	Total number of implants -	662
B.	Number of devices reimplanted -	7
C.	Total number of devices -	655
D.	Active/potentially active status	
1.	Active status confirmed (Recent follow-up reports, ≤ 1 year)	6
2.	Lost-to-Follow-up (No recent follow-up reports, > 1 year)	73
E.	Inactive Status (Reported out of service)	
1.	Returned to Medtronic -	508
2.	Patient death (Device location unknown)	35
3.	Device explanted (Device location unknown)	18
4.	Device buried with patient -	14
5.	Device buried in landfill -	1

ATTACHMENT II
EXPLANTS NOT PREVIOUSLY REPORTED

S/N	HOSPITAL CODE	MD. CODE	PAT. CODE	REASON FOR EXPLANT	DATE OF EXPLANT, DEATH, RETURN	STATUS OF IPG	APPROXIMATE PATIENT AGE AT EXPLANT/DEATH
3R00008	2003	2004	1029	UNKNOWN	3/29/96	RETURNED/OK	75
3R00020	20[illegible]	2004	1160	PATIENT EXPIRED	3/25/96	RETURNED/OK	80
3R00055	1060	1006	1318	PROGRAMMING PROBLEM	3/5/96	RETURNED/ CORRODED CONNECTOR BLOCK	68
3R00109	1019	1021	1010	UNKNOWN	REC'D BY MEDTRONIC 9/23/96	RETURNED/OK	78
4R00211	1013	1014	2625	MEDICAL JUDGEMENT/ SYSTEM UPGRADE	1/17/96	RETURNED/OK	64
4R00292	1027	2147	2980	CAPTURE AND SENSING DIFFICULTY	2/28/96	RETURNED/OK	70
4R00316	1017	1019	3567	PATIENT EXPIRED	5/15/96	ANALYSIS STILL IN PROGRESS	82
6R00307	3159	3196	3554	UNKNOWN	REC'D BY MEDTRONIC 10/5/95	RETURNED/OK	62

ATTACHMENT III

EXPLANATION OF MODEL 9000 FAILURES
SINCE REPORT OF OCTOBER, 1995

One (1) failure has been identified (see Attachment II) since publication of the October, 1995 summary. There have been a total of One Hundred Fifty-One (151) failures since the unit was introduced in 1972.

FAILURE	NUMBER
Corroded Connector Block	1

ATTACHMENT IV

STATEMENT OF MODEL 9000 ACCOUNTABILITY

An objective of the Model 9000 Investigational Program has been to evaluate the system of patient registration, follow-up and recovery of the pulse generator. Difficulties in maintaining complete patient follow-up have been reported previously. Continued reliance has had to be placed on follow-up information obtained by telephone and Medtronic Returned Product Department since routine data forms are often not returned to Medtronic per the protocol agreement. Therefore, in spite of efforts by Medtronic, total and continuous accountability for the status of all patients with Model 9000 pulse generators cannot be maintained. However, return of explanted devices to Medtronic is likely.

Medtronic

Medtronic, Inc.
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November 1, 1991

United States Nuclear Regulatory Commission
Medical, Academic, and Commercial Use Safety Branch
Division of Industrial and Medical Nuclear Safety
Washington, D.C. 20555

ATTN: Patricia C. Vacca

Dear Ms. Vacca:

Enclosed is a summary of the clinical evaluation study of the Medtronic Implantable Demand ISOTOPIC PULSE GENERATOR, Laurens-Alcatel Model 9000. The closing date for the data in this report is October 1, 1991.

This report is submitted as an update of the Summary of Clinical Evaluation Study submitted to the United States Nuclear Regulatory Commission on November 1, 1990.

If you have any questions regarding this report, please contact me at 1-800-328-2518 (x6232).
Thank you.

Sincerely,

MEDTRONIC, INC.

Larry A. Paulson, P.E.
Senior Product Performance Engineer
Clinical Operations

DATE: 11-12-96

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER: BJ HOLT

LICENSEE: MEDTRONIC

LICENSE NUMBER: SNM-1156

The following correspondence has been received from the above licensee and it is not clear what action(s) is(are) required: Please review this correspondence and indicate which of the following applies, and please return to Debbie Hersey, as soon as possible.

☐ Additional Information to Control No. _____.
Process in as a new action, additional information, and no fee required.

☐ Process as new licensing action. Review has already been started on Control No. _____ and this information cannot be combined with current in-house action.

☐ Can be combined with Control No. _____. Review has not started.

☑ Appears to be information for the license file - file it. BJH

☐ Licensee is adding Nuclear Pharmacists.

Amendment is necessary _____. Amendment is not necessary _____.
(Information for license file)

☐ Licensee is adding authorized users.

A check is included _____. No check is included _____.

Amendment is necessary _____. Amendment is not necessary _____.
(This is a Notification)

☐ Process in as a new licensing action:

A. Amendment _____
B. Renewal _____
C. New License Application _____

☑ Other: Licensee Required Report

Thank You For Your Help!!! 10/16/96