

Our Lady of Lourdes Medical Center

1600 Haddon Avenue • Camden, New Jersey 08103
(609) 757-3500

070-02989

*Rec'd NMSS/HA
6-29-88
Alacca*

- || Southern New Jersey Cardiac Diagnostic and Surgical Center
- || Regional Dialysis and Transplantation Center
- || Regional Perinatal Center
- || Regional Rehabilitation Center

X

June 16, 1988

RECEIVED
'88 JUN 27 AM 11:27
U.S. DEPT. OF HEALTH
LIC. FEE EXEMPT

Director, Office of Nuclear Material
Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Gentlemen:

The following information is submitted in application for renewal of Nuclear Pacemaker License.

- A. License number - SNM-1923
- B. Our Lady of Lourdes Medical Center
1600 Haddon Avenue
Camden, New Jersey 08103
- C. Pacemakers to be authorized:
Cordis Nuclear Omni-Stanacor Pacemaker Model # 184A Series # 205
Model # 184A Series # P11530
- D. The principal reasons for renewing pacemaker licenses are to follow patients with implanted pacemakers and to return explanted pacemakers to the manufacturer for proper disposal (but not to implant pacemakers in the future).
- E. Physicians responsible for the program:

Francisco Enriquez, M.D., Marvin Grossman, M.D., Ernest E. Flegal, M.D.,
Vincent McDermott, Jr., M.D., and Charles P. Lisa, M.D.

Our Lady of Lourdes Medical Center hereby requests a renewal license in accordance with this application.

Signed:

Applicant: Our Lady of Lourdes Medical Center

By: *Sister M. Elizabeth Corry*
Sister M. Elizabeth Corry
Administrator

FEE EXEMPT

pacemaker # 29-06431-01 (7c)

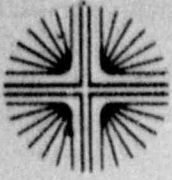
*6/27/88
Jun 17
Manning*

Sponsored by The Franciscan Sisters of Allegany, New York
Member Allegany Health System, Inc.
A major teaching affiliate of Jefferson Medical College of Thomas Jefferson University

OFFICIAL RECORD COPY ML18

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8912070081 880616
REG1 LIC70
SNM-1923
PDR



Our Lady of Lourdes Medical Center

1600 Haddon Avenue • Camden, New Jersey 08103
(609) 757-3500

NO 70-2989

- || Southern New Jersey Cardiac Diagnostic and Surgical Center
- || Regional Dialysis and Transplantation Center
- || Regional Perinatal Center
- || Regional Rehabilitation Center

'83 JUL 13 P2:51

June 23, 1983

U.S. Nuclear Regulatory Commission
Material Licensing Branch
Washington, D.C. 20555

Re: DOCKET NO. 70-2319
New License for Special Nuclear Material

Gentlemen:

In reference to a recent telephone conversation, a written request is being made to apply for a new SNM license.

In May of 1976, we applied for a license to participate in a program to implant Coratomic C101 Isotopic Powered Pacemakers - License # SNM 1650. Subsequently, we also applied for amendments to use Cordis Nuclear Omni-Stanicor Model 184A, Biotronic, and Medtronic Model 9000 cardiac pacemakers.

We will not be implanting any more Nuclear Pacemakers. We have four patients in whom Cordis Nuclear Pacemakers are functioning now. These patients are checked for pacemaker function by Anthropometrics on a monthly basis. They are also checked by their family physicians or cardiologists routinely. We will continue the follow-up reporting and recovery procedures during the life of the patient and until the pacemaker is recovered and returned to the manufacturer per his instructions. We will also continue to have an emergency procedure, should a patient have an emergency, which has been developed with the hospital operators and the pacemaker coordinator.

All physicians listed on the previous SNM license are current.

Sister M. Elizabeth Corry, OSF has been transferred and Anthony Peters, Administrator has assumed these responsibilities.

Please let us know if further information is needed.

Sincerely,

Anthony Peters

Anthony Peters
Administrator

Francisco Enriquez, M.D.
Francisco Enriquez, M.D.
General Surgeon

FEE EXEMPT \$
DML 29-06431-01

22523

AP:vf

Region I 07/13/83

70-2319

Regulatory Docket File

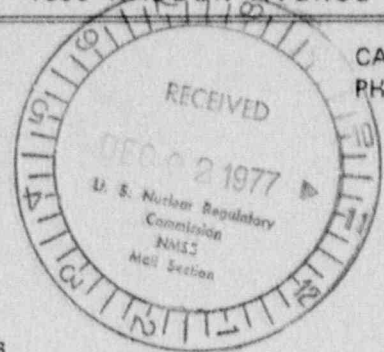


"The Body is often curable, the Soul is ever so"

Our Lady of Lourdes Hospital

1600 HADDON AVENUE

CAMDEN, N. J. 08103
PHONE 808-962-1888



607-757-3500
Exp 7/31/81
Cat EX
7/3

November 3, 1977

Radioisotopes Licensing Branch
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

ATTENTION: Mrs. Pat Vacca

RE: Amendment of our license -number SNM-1650- to include the Medtronic Model 9000 Isotopic Pulse Generator

Gentlemen:

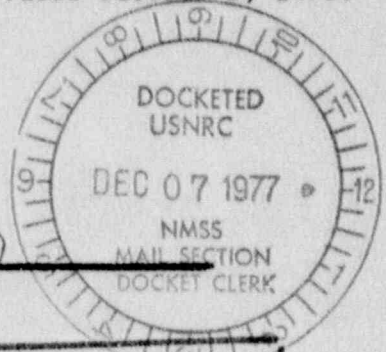
We wish to amend our license to include the Medtronic Model 9000. We are familiar with the Medtronic Model 9000 protocol dated March 1, 1973, revised October 1, 1975. We wish to implant ten model 9000s annually.

Signed:

Applicant : by

Sister M. Elizabeth Corry

Sister M. Elizabeth Corry, OSF



Physicians Responsible for Study:

Francisco Enriquez, M.D.

Francisco Enriquez, M.D.

Charles P. Liba

Charles P. Liba, M.D.

Marvin Grossman

Marvin Grossman, M.D.

Ernest E. Flegel

Ernest E. Flegel, M.D.

Vincent T. McDermott Jr.

Vincent T. McDermott Jr., M.D.

RECEIVED BY LFMB	
Date	12/6/77
Time	noon
By	Wess
From	
Cy to	
Action Compl	12/6/77

08198



"The Body is often curable, the Soul is ever so"

Our Lady of Lourdes Hospital

1600 HADDON AVENUE

CAMDEN, N. J. 08103
PHONE 609 ~~757-3500~~
757-3500

October 5, 1976

Chief, Materials Branch
Directorate of Licensing Regulations
Nuclear Regulatory Agency
Washington, D.C. 20545

Subject: Amendment to License No. SNM-1650 for implantation of
Nuclear powered pacemakers.

Dear Sir:

Since Our Lady of Lourdes Hospital is licensed to implant Nuclear Pace-
makers under the license number SNM-1650, dated July 16, 1976, we re-
quest an amendment for our license that would permit us to include the
Cordis Nuclear Omni-Stanicor Model No. 184 Catalog No. 307-CO5. We
will follow explicitly the master protocol, dated October 30, 1974,
provided by the Cordis Corporation and approved by your office. You
can be assured that all institutional commitments previously submitted
are binding. Any changes in this initial commitment are enclosed.

If any additional forms or information are required, please notify us
as soon as possible.

Signed:

Applicant: John Elizabeth Corry M.D.
Our Lady of Lourdes Hospital Adm.
1600 Haddon Avenue
Camden, NJ 08103

By: Francisco Enriquez M.D.
Francisco Enriquez, M.D.
General Surgeon

RECEIVED BY FMB
Date: 10-13-76
Time: 4:00 pm
By: [Signature]
FROM: [Signature]
City: Camden
ACTION: [Signature] 10-13-76

RECEIVED
FNB
OCT 14 1976
REGISTRY
LEGAL CLERK

1713

Regulatory File Cr.

ed 76 P-6



"The Body is often curable, the Soul is ever so"

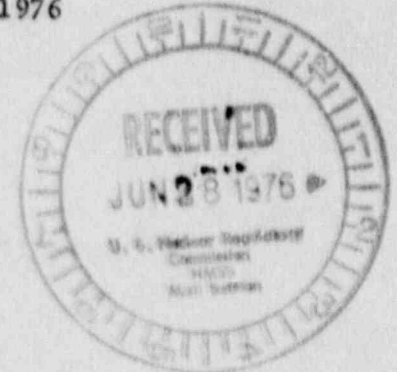
Our Lady of Lourdes Hospital

1600 HADDON AVENUE

CAMDEN, N. J. 08103

PHONE 609 963-4300

May 26, 1976



Mrs. Patricia C. Vacca
Division of Fuel Cycle and Materials
Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mrs. Vacca:

RE: Application for license to participate in an investigational program involving the implantation of Coratomic C-101 Isotopic Powered Pacemakers, each containing 250 milligrams of Pu-238 (< 4.3 curies)

The following information is submitted in application for a license to participate in the investigational program utilizing the Coratomic C-101 Isotopic Powered Pacer:

1. Applicant: Our Lady of Lourdes Hospital
1600 Haddon Avenue
Camden, New Jersey 08103
 2. Physicians responsible for study:
 - a. Name - Francisco Enriquez, M.D.
Office address - 8 S. Haddon Ave., Haddonfield, N.J. 08033
Telephone - (609) 429-2212
Specialty Board Certification - Board eligible Thoracic Surgery
Training - 1st and 2nd year surgical residency at Newton Wellesly Hospital, Newton, Mass. 1959-1961; 3rd year surgical residency at the Genesee Hospital in Rochester, N.Y. 1961-1962; 1st year Thoracic and Cardiovascular Surgical Resident at the Presbyterian Hospital, Philadelphia, Penna. 1962-1963; 2nd year Thoracic and Cardiovascular Surgical Resident Temple University Hospital, Philadelphia, Penna. 1963-1964; Chief Resident Thoracic and Cardiovascular Surgery Temple University Hospital, Phila., Pa. 1964-1965
Position with applicant - attending staff with 9 years experience in the clinical implantation and follow-up of cardiac pacers.
- | | |
|---------------------------------------|-----|
| Total number of pacers implanted | 275 |
| Total number done at this institution | 50 |

FEE EXEMPT

*possessor
agreement file
29-06431-01 (70)*

Allen

1081

June 76 - P-20



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Our Lady of Lourdes Hospital

1600 HADDON AVENUE

CAMDEN, N. J. 08103

PHONE 609 963-4300

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- b. Name - Marvin Grossman, M.D.
Office address - 409 East State Highway #70, Cherry Hill, N.J.
Telephone number - (609) 428-5857
State in which licensed to practice - New Jersey
Specialty Board Certification - American Board of Internal Medicine;
Subspecialty in Cardiovascular Disease
Training - Residency in Internal Medicine, Great Lakes Naval Hospital
1964-1967; Fellowship in Cardiology, Philadelphia Naval Hospital,
1967-1969
Position with Applicant: Chief of Cardiology
- c. Name - Ernest E. Flegel, M.D.
Office address - 501 Haddon Ave., Haddonfield, N.J. 08033
Telephone number - (609) 429-1110
State in which licensed to practice - New Jersey, Pennsylvania
Specialty Board Certification - Board Eligible Cardiology
Training - Residency in Internal Medicine, Jefferson Medical College
Hospital, Phila., Penna. 1966-1967; Jefferson Medical College
Hospital (Philadelphia General Hospital Division), Phila., Pa.
1969-1970; Chief Resident in Internal Medicine, Jefferson Medical
College (Philadelphia General Hospital Division), Phila., Pa.
1970-1971; Fellowship in Cardiology Jefferson Medical College
Hospital, Philadelphia, Penna. 1971-1973
Position with Applicant - Attending Physician
- d. Name - Vincent T. McDermott, Jr., M.D.
Office address - 1533 Haddon Ave., Camden, N.J. 08103
Telephone number - (609) 964-3110
State in which licensed to practice - New Jersey
Specialty Board Certification - Eligible in Internal Medicine
Training - Residency in Internal Medicine, St. Michaels Hospital,
Newark, N.J. 1961-1963; Cardiology Fellowship Hahnemann Hospital,
Phila., Pa. 1963-1965.
Position with Applicant - Associate Staff



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Our Lady of Lourdes Hospital

1600 HADDON AVENUE

CAMDEN, N. J. 08103

PHONE 609 963-4300

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- e. Name - Charles P. Lisa, M.D.
Office address - 937 Haddon Ave., Haddonfield, N.J. 08033
Telephone number - (609) 795-0299
State in which licensed to practice - New Jersey, Pennsylvania
Specialty Board Certification - American Board of Internal Medicine,
Subspecialty in Cardiovascular Disease
Training - Residency in Medicine at Hahnemann Medical College and
Hospital, Phila., Penna. 1968-1970; Cardiology Fellowship Indiana
University Hospital, Indianapolis, Indiana 1970-1971; Cardiology
Fellowship Hahnemann Medical College Hospital, Philadelphia, Pa.,
1973-1974
Position with Applicant - Program Director Department of Medicine
- f. Name - Ralph Caccse, M.D.
Office address - 1600 Haddon Ave., Camden, N.J.
Telephone number - (609) 963-4300
State in which licensed to practice - New Jersey
Specialty Board Certification - American Board of Radiology
Endorsed by American Nuclear Medicine Society 1957
Position with Applicant - Radiation Safety Officer Isotopic License No.
20-06431 -01
3. Protocol to be followed:
HUMAN CLINICAL PROTOCOL FOR THE CORATOMIC C-101 RADIOISOTOPE
POWERED CARDIAC PACER DATED November 1, 1975 (On file at N.R.C.)
4. A maximum of 10 Coratomic C-101 pacemakers are requested to be implanted
annually during the study.
5. The physical facilities and equipment at Our Lady of Lourdes Hospital perti-
nent to the Coratomic C-101 study program include the following:
- a. Pacemakers are implanted either in the Cardiac Catheterization Laboratory
or in the Surgical Department, depending on whether Transvenous or
Epicardial leads are used and if the surgery is an initial pacemaker implant
or a battery replacement.



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- b. The Coronary Care Unit into which the patient is moved immediately after thoracic surgery contains 8 beds, all of which are equipped with hardware monitoring to a central monitor equipped with write out and alarm. The unit also contains 1 portable defibrillator, 3 5880A external medtronic pacers, and 1 MedData high rate atrial pacing unit.
6. Our Lady of Lourdes Hospital Present Pacemaker Implantation and Follow-up Program

At the present time the stimulation thresholds and sensing thresholds of all pacemaker implants are measured intra-cardiac with a Cordis Chronocor III External Pacing Unit. This is done by nursing personnel from the operating room under the guidance of the implanting surgeon. At each implant an electrocardiogram is obtained and a follow-up and reporting procedure is utilized during the life of the battery pacer. Present examination times at which electrocardiograms are taken at initial implant, approximately 24 hours after implant, at time of discharge, at approximately the third month after implant, and once every six months thereafter. The most commonly used pacemaker at present is the Cordis Omnicor. Records are kept in the office of the patients' referring physicians and duplicate records are kept on file at the hospital.

7. Maintenance of Records of Implantation and Follow-up of Patients for the C-101 Program

Careful follow-up and recording procedures will be followed during the life of the patient or until the C-101 pacemaker is removed. This follow-up will be separate from the routine hospital records kept on every patient. At each examination period an electrocardiogram will be obtained with the application of a magnet to induce fixed rate operation of the pacer. Follow-up examination will be conducted at the following intervals after implant. At one month, the third month, and at least once every six months thereafter until removal of the pacer.

The following forms will be executed as discussed in the Coratomic C-101 November 1, 1975 Protocol: Registration and Implantation Data Form, Follow-up Data Form, Pacer Failure and Removal or Patient Death Form, Informed Consent for Surgical Implantation of Radioisotope Powered



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PHONE 609 963-4300

Page 5

Cardiac Pacer Form, Donor Cards for Adults or Donor Cards for Minors, properly executed Instructions for Hospital Telephone Operator and Patient Identification Cards. The instructions for the hospital telephone operator is shown as Attachment 1 of this submission.

Records will be kept in the offices of the physicians responsible for the individual patient examinations. These records will also be made available to referring cardiologists and duplicate records will be kept on file at the hospital.

8. Control Procedures

Our Lady of Lourdes Hospital will establish appropriate control procedures and be responsible for the physical security of the pacemaker while in possession of the applicant. These procedures will include keeping track by serial number of the location of each pacemaker and requiring that they be kept under lock and key when not being used to guard against loss or theft. Our Lady of Lourdes Hospital will also assure that all activities are conducted in accordance with the regulations under Title 10, Code of Federal Regulations, Part 70.

9. Emergency Procedures

A pacemaker coordinator will be assigned and will be responsible for giving the hospital telephone operators written instructions concerning the notification of appropriate individuals upon receipt of emergency report and inquiry concerning a pacemaker bearer. The coordinator will also be responsible for personal discussions with each telephone operator. The form used for this purpose is shown as Attachment I. The pacemaker coordinator will be: Mrs. Helen Blackwell, R.N., Head Nurse of the Coronary Care Unit.

10. Physicians Responsible

The physicians responsible for an participating in the study have certified that they are familiar with the Coratomic C-101 Protocol and the Coratomic C-101 Isotopic Pacer. They understand that the issuing of a license amendment is conditional upon the following of the Protocol.



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Our Lady of Lourdes Hospital

1600 HADDON AVENUE

CAMDEN, N. J. 08103

PHONE 609 963-4300

Page 6

11. Our Lady of Lourdes Hospital agrees to continue the follow-up reporting and recovery procedures during the life of the patient and until the pacemaker is recovered and returned to Coratomic Inc., P.O. Box 434, Indiana, Penna. 15701, even in the event the physicians named in the application to participate in the study are no longer associated with the applicant.
12. The packaging, labeling and shipping instructions furnished by Coratomic Inc. will be followed upon return of the pacemaker for approved disposal.
13. Our Lady of Lourdes Hospital hereby requests a license to receive, possess, store, and implant the Coratomic C-101 Isotopic Powered Pacemaker in accordance with this application.

Physicians responsible for the
investigational program:

Signed:

Applicant

Our Lady of Lourdes Hospital

Francisco Enriquez, M.D.
Francisco Enriquez, M.D.

By

Sister M. Elizabeth Corry
Sister M. Elizabeth Corry, OSF
Administrator

Marvin Grossman, M.D.
Marvin Grossman, M.D.

Ernest E. Flegel, M.D.
Ernest E. Flegel, M.D.

Vincent T. McDermott, Jr., M.D.
Vincent T. McDermott, Jr., M.D.

Charles P. Lisa, M.D.
Charles P. Lisa, M.D.

ATTACHMENT I

INSTRUCTIONS FOR HOSPITAL OR CLINIC TELEPHONE OPERATORS
CORATOMIC C-101 ISOTOPIC PULSE GENERATOR

Project Nuclear Pacemaker

Instructions to Operator:

1. Accept any collect call with reference to "Project Nuclear Pacemaker."
2. Any call concerning "Project Nuclear Pacemaker" involves a patient with a nuclear pacer and requires immediate action to insure that there is no danger of radiation exposure and recovery of the nuclear pacer.
3. Obtain as much information from the caller as is possible including:

Caller's name and where he may be reached.

Patient's name, status, and where he may be reached.

Attending physician (if any) and where he may be reached.

Information from Patient I. D. Card

Patient's Social Security Number _____

Date of Implant _____

Pacer Serial Number _____

Implanting Physician _____

4. Notify immediately: Francisco Enriquez, M.D.
8 S. Haddon Ave., Haddonfield, NJ 08033
(609) 429-2212

If he cannot be reached, notify: Marvin Grossman, M.D.
409 East State Highway #70
Cherry Hill, N.J.
(609) 428-5857

If he cannot be reached notify: Mrs. Helen Blackwell, R.N.,
(Pacemaker Coordinator) Head Nurse, Coronary Care Unit
(609) 757-3500

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 22160
Status Code: 2
Fee Category: EX 7C
Exp. Date: 19880831
Fee Comments: _____

LICENSE FEE TRANSMITTAL

A. REGION

APPLICATION ATTACHED

Applicant/Licensee: OUR LADY OF LOURDES MEDICAL CTR.
Received Date: 880623
Docket No: 7002989
Control No.: 120560
License No.: SNM-1923
Action Type: Renewal

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed M. Moriarty
Date 6-24-88

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License _____

Permittee # 29-00431-01

3. OTHER _____

Signed Ms. Messer
Date 4/27/88