



## GRANDVIEW HOSPITAL

405 GRAND AVENUE • DAYTON, OHIO 45405  
RICHARD J. MINOR • EXECUTIVE DIRECTOR

Regulatory

File Cx.

January 16, 1976



Mr. J. R. Mason  
Chief, Materials Branch  
Division of Materials and Fuel  
Cycle Facility Licensing  
U.S. Nuclear Regulatory Commission  
Washington, D. C. 20545

Dear Mr. Mason:

Re: Application for a license to participate in a research study involving the implantation of Coratomic C-101 Series isotopic powered pacemakers, each containing 250 milligrams of PU-238 (less than 4.3 curies).

The following information is submitted in application for a license to participate in the investigational program utilizing the Coratomic C-101 Series isotopic powered pacer.

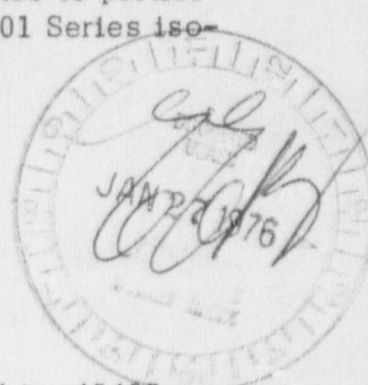
1. Applicant: Grandview Hospital  
405 Grand Avenue  
Dayton, Ohio 45405

2. Physicians Responsible for Study:

Name - James G. Laws, D.O.  
Office Address - 531 Belmonte Park - North, Dayton, Ohio 45405  
Telephone Number - (513) 222-6012  
BNDD Number AL4869509 -- Ohio License Number 2048

States licensed in which to practice - Ohio, Texas, Missouri and Pennsylvania.

Specialty Board Certification - American Board of Osteopathic Internists, written examination passed, oral examination passed.



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Training - rotating internship at Stevens Park Hospital in Dallas, Texas, from 1970 to 1971; two year medical residency at Grandview Hospital in Dayton, Ohio, from 1971 to 1973; two year cardiology fellowship at Hahnemann Hospital in Philadelphia, Pennsylvania, from 1973 to 1975.

Position with Applicant - Active Medical Staff provides experience in the clinical implantation and follow up of pacemakers:  
Personal pacemaker experience - 4 years  
Total number of implants done - 100 while at Hahnemann  
Total number done at this facility - 40 transvenous pacers  
Director of Cardiac Catheterization Laboratory.

Name - Robert W. Jones, D.O.  
Office Address - 325 Grand Avenue, Dayton, Ohio 45405  
Telephone Number - (513) 224-1764  
BNDD Number AJ6223248 -- Ohio License Number 2252

States licensed in which to practice - Ohio, Texas, Kansas, and Missouri.

Training - Kansas City College of Osteopathic Medicine, graduated Doctor of Osteopathy in June, 1968; twelve month rotating internship at Lakeside Hospital, Kansas City, Missouri, from 1968 to 1969; two year General Surgery training at Lakeside Hospital, Kansas City, Missouri, from 1969 to 1971; two year General Surgery residency at Grandview Hospital, Dayton, Ohio, from 1971 to 1973; twelve month fellowship under J. F. Howell, M.D., in cardiovascular and thoracic surgery at Methodist Hospital, Texas Medical Center, Houston, Texas, from 1973 to 1974.

Private practice began September, 1974.

Position with Applicant - Active Medical Staff.

Previous experience in clinical implantation of pacemakers at Lakeside Hospital, Kansas City, Missouri; Methodist Hospital, Houston, Texas; and Grandview Hospital, Dayton, Ohio.

During General Surgery residency assisted in and performed 20 implants of pacemakers; during fellowship at Methodist Hospital assisted and participated in approximately 50 to 60 pacemaker implants. Implanted since entering practice - have done five epicardial pacemakers and ten permanent transvenous pacemakers.



Name - Leslie R. White, D.O.  
Office Address - 359 Forest Avenue, Dayton, Ohio 45405  
Telephone Number - (513) 222-6051  
BNDD Number AW4369446 -- Ohio License Number 1373

State licensed in which to practice - Ohio.

Specialty Board Certification - American Osteopathic Board of  
Internal Medicine.

Training - residency in Internal Medicine, Grandview Hospital,  
Dayton, Ohio, from 1960 to 1963.

Position with Applicant - Director of E.K.G. and Non-Evasive  
Laboratory, 1972 - 1976.

Name - Julian Milton Zimmerman, D.O.  
Office Address - 2 Yale Avenue, Dayton, Ohio 45406  
Telephone Number - (513) 274-2145  
BNDD Number AZ2872679 -- Ohio License Number 107

State licensed in which to practice - Ohio.

Specialty Board Certification - American Osteopathic Board of In-  
ternal Medicine, Chairman, Isotopic Committee - Hospital Iso-  
tope License Number 34-06904-01.

Position with Applicant - Director of Nuclear Medicine Department,  
Chairman, Isotopic Use Committee, Hospital Isotope License  
Number 34-06904-01, Radiation Safety Officer.

3. Protocol to be followed:

HUMAN CLINICAL PROTOCOL FOR THE CORATOMIC C-101 SERIES  
RADIOISOTOPE POWERED CARDIAC PACER, dated November 1, 1975.  
(On file at NRC.)

4. A maximum of 30 Coratomic C-101 Series pacemakers is requested  
to be implanted annually during this study.

5. The physical facilities and equipment at Grandview Hospital pertinent

to the Coratomic C-101 study program include the following:

- a. Pacemakers are implanted in the cardiac catheterization laboratory which has the capability for surgical implantation such as epicardial leads.
- b. The intensive care unit, which the patient is moved to immediately after pacer implant, includes 9 beds with Burdick equipment, all 9 of which are equipped with a hardwire monitoring type of equipment. There are 2 portable defibrillators and 4 external pacemakers available.
- c. The step down cardiac care unit contains 8 beds with 2 beds per room. These are telemetered monitored units. These telemetry units (Care 4000) are monitored in the intensive care unit. External power pacemakers are on standby at all times in this unit. There are two (2) Burdick portable defibrillators in close proximity to this unit.

6. Grandview Hospital's present pacemaker implantation and follow-up program:

At the time of initial pacemaker implant or pacemaker replacement, the stimulation thresholds and sensing thresholds of all implants are measured intra-cardiac with the Cordis Synchrocorder II. Personnel from the Cardiology Department measure these potentials. At each implant, an electrocardiogram is obtained and follow-up reporting procedure is utilized during the life of the pacer battery. Present examination times at which electrocardiograms are taken are at initial implant, then again approximately 24 hours after implant, at time of discharge, at three-month intervals, and at six months after one year post implant. The hospital's Pacemaker Clinic is as outlined above. All records pertinent to pacemaker follow up will be kept on file in the Pacemaker Clinic in Grandview Hospital.

7. Maintenance of records of implantation and follow up of patients for C-101 Series program:

The Pacemaker Clinic will be responsible for the follow up and recording procedures during the life of the patient or until the



C-101 Series 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, three months, and six months following the insertion of the pacer until removal. The Pacemaker Clinic will follow the pacemaker at six month intervals. It is recognized that general medical care may be more frequent than this, but this is the minimal time between tests of pacer function for purposes of this study.

Forms to be used will be processed as discussed in the Coratomic C-101 Series, November 1, 1975 Protocol: Registration and Implantation Data Form, Follow-Up Data Form, Pacer Failure and Removal of Patient Death Form, Informed Consent for Surgical Implantation of Radioisotope Powered Cardiac Pacer Form, Donor Cards for Adults or Donor Cards for Minors, properly executed, Instructions for Hospital Telephone Operator and Patient Identification Cards. The instruction for the hospital telephone operator is shown as Attachment 1 of this submission.

Grandview Hospital's Medical Records Department will keep all records in the central data center and duplicate records will be kept in the offices of the physicians responsible for the individual patient examinations. These records will also be made available to the referring Cardiologist.

8. Control Procedures:

The C-101 pacemaker will be kept under lock and key when not being used to guard against loss or theft. An appropriate control procedure will be initiated for keeping track of serial numbers and the location of each C-101 pacemaker. Grandview 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, Karen Sauer, R.N., 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 1.

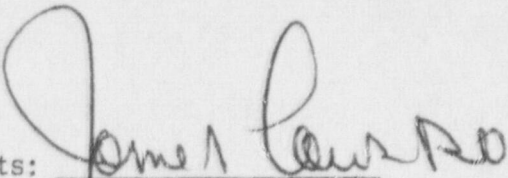
10. Physicians Responsible:

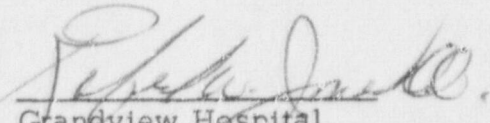
The physicians responsible for and participating in the study have certified that they are familiar with the Coratomic C-101 Series Protocol and the Coratomic C-101 Series Pacer. They understand that the issuing of a license amendment is conditional upon following of the Protocol.

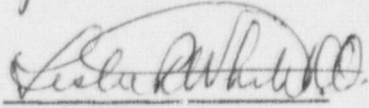
11. Grandview Hospital agrees to continue the follow-up reporting and recovery procedures during the life of the patient and until the pacemaker is recovered and returned to Coratomic, Inc., P.O. Box 434, Indiana, Pennsylvania 15701, even in the event of the physicians named in the application to participate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

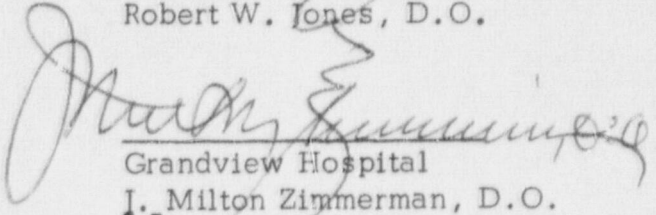
Signed:

Applicants:

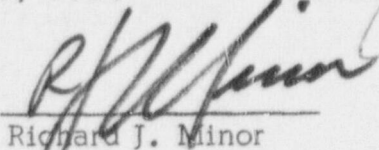
  
Grandview Hospital  
James G. Laws, D.O.

  
Grandview Hospital  
Robert W. Jones, D.O.

  
Grandview Hospital  
Leslie R. White, D.O.

  
Grandview Hospital  
I. Milton Zimmerman, D.O.

By:

  
Richard J. Minor  
Executive Director  
Grandview Hospital

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Attachment



ATTACHMENT 1

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 No. \_\_\_\_\_

Date of Implant \_\_\_\_\_

Pacer Serial Number \_\_\_\_\_

4. Notify immediately: James G. Laws, D.O., 531 Belmonte Park - North,  
Dayton, Ohio 45405 Phone: (513) 222-6012,  
222-5205 or 226-3200.

If he cannot be reached, notify: Leslie R. White, D.O., 359 Forest Avenue,  
Dayton, Ohio 45405 Phone: (513) 222-6051  
or 299-1531.

If he cannot be reached, notify: Robert W. Jones, D.O., 325 Grand Avenue,  
Dayton, Ohio 45405 Phone: (513) 224-1764  
or 429-1412.

If he cannot be reached, notify: J. Milton Zimmerman, D.O., 2 Yale Avenue,  
Dayton, Ohio 45406 Phone: (513) 274-2145  
or 299-2212.

If none of these doctors can be reached, contact physician on duty for the Intensive Care Unit; inform him that this involves a nuclear pacer; and advise him of the information you have and the urgency of the matter.