



# North Kansas City Memorial Hospital

The Medical and Dental Staff

70-2521

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

Re: Application for a license to participate in the  
investigational implantation of Cordis Nuclear  
Omni-Stanacor #184 nuclear powered pacemakers

Gentlemen:

The following information is submitted in application for a  
license to participate in the investigational program utiliz-  
ing Cordis Nuclear Omni-Stanacor nuclear powered pacemakers.

1. Applicant: North Kansas City Hospital  
2800 Hospital Drive  
North Kansas City MO 64116

2. Physicians responsible for study:

A. Name: Robert D. Williams, M.D.

Office Address: 6700 Troost, Suite 348  
Kansas City, MO 64131

Office Telephone No.: (816) 333-9332

State in which licensed to practice: Missouri and Kansas

Speciality board certification: American Board of Surgery, 1965  
American Board of Thoracic Surgery, 1965

Position with applicant: Active Staff in Thoracic Surgery

Experience in the clinical implantation and follow-up of pacemakers: Resident in general and thoracic surgery at the University of Mississippi (1960-1965)

Has implanted approximately 250 pacemakers since 1965 with the greatest majority implanted at North Kansas City Memorial Hospital. Is currently following about 35 pacemaker patients.

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## North Kansas City Memorial Hospital

The Medical and Dental Staff

- B. Comer Bates, M.D.  
2700 Hospital Drive  
North Kansas City, MO 64116  
(816) 421-4240

Licensed to practice in Missouri

Board certification with American College of Physicians (1945)

Position with applicant: Active Staff Internal Medicine

Experience in the clinical implantation and follow-up of pacemakers: Resident in Internal Medicine at the Cleveland Clinic, Cleveland, Ohio 1949

- C. Larry E. Benson, M.D.  
2700 Hospital Drive  
North Kansas City, MO 64116  
(816) 421-4240

Licensed to practice in Missouri and Kansas

Board certification with American Board of Internal Medicine (1966); American College of Physicians (1975)

Position with applicant: Active Staff in Internal Medicine

Experience in the clinical implantation and follow-up of pacemakers: Resident in Internal Medicine at University of Kansas (1965)

- D. Bryan T. Bownik, M.D.  
2700 Hospital Drive  
North Kansas City, MO 64116  
(816) 421-4240

Licensed to practice in Missouri

Board certification with American College of Physicians, 1973  
American Board of Internal Medicine, 1976

Position with applicant: Active Staff in Internal Medicine

Experience in the clinical implantation and follow-up of pacemakers: Resident in Internal Medicine at the University of Columbia, New York, N.Y. (1976)



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- E. Newton C. McCluggage, M.D.  
2700 Hospital Drive  
North Kansas City, MO 64116  
(816) 421-4240

Licensed to practice in Missouri and Kansas

Board certification with American Medical Association (1965)

Position with applicant: Active Staff in Internal Medicine

Experience in the clinical implantation and follow-up  
of pacemakers: Resident in Internal Medicine at Kansas  
City General Hospital, 1969

Doctors Bates, Benson, Bownik and McCluggage comprise the  
largest group in Internal Medicine at North Kansas City  
Memorial Hospital. Because of that, they have referred  
the greatest majority of both temporary and permanent  
pacemakers implants. The group is currently following 30  
pacemaker patients (approximately).

- F. Robert H. Hodge, M.D.  
2029 Burlington Street  
North Kansas City, MO 64116  
(816) 474-9232

Licensed to practice in Missouri and Colorado

Board certification with Diplomate American Board of Internal  
Medicine (1956)

Position with applicant: Active Staff in Internal Medicine.

Experience in the clinical implantation and follow-up of  
pacemakers: Resident in Internal Medicine at Kansas City  
General Hospital, Kansas City, Missouri, 1956.

- G. William R. Prather, M.D.  
2029 Burlington Street  
North Kansas City, MO 64116  
(816) 474-9232

Licensed to practice in Missouri and Colorado





## North Kansas City Memorial Hospital

The Medical and Dental Staff

Board certification: Associate American Board of Internal Medicine (1976). Pending full fellowship American Board of Internal Medicine (July, 1977).

Position with applicant: Active Staff in Internal Medicine.

Experience in the clinical implantation and follow-up of pacemakers: Resident in Internal Medicine at the University of Colorado, Boulder, Colorado (1976).

Doctors Hodge and Prather formed their partnership in August of 1976. Prior to that time, only Doctor Hodge referred patients for temporary or permanent pacemakers. Approximately fifty (50) patients have been referred for permanent implant with twenty (20) patients are currently being followed.

3. Protocol to be followed: Master Protocol for Clinical Evaluation of the Programmable Cordis Nuclear Omni-Stanacor Pacemaker dated October 30, 1974.
4. Number of Cordis Nuclear Omni-Stanacor #184 pacemakers to be implanted annually during the study: Six (6).
5. Description of physical facilities and equipment at the applicant hospital or medical institution for implantation and follow-up of pacemakers:
  - A. Pacemakers with transvenous leads are implanted in the Radiology Department and pacemakers with myocardial leads are implanted in the Surgical Suite. The Radiology Department has a General Electric fluoroscope with image intensifier which is used routinely in all radiology procedures. The Radiology Department and all operating rooms used for surgery have electrocardiographs with oscilloscope and written copy readouts, model 156B external pacemaker for capture and sensing threshold measurements, model 5980 external pacemakers for temporary pacing, and American Optical portable defibrillators.
  - B. The Cardiac Care Unit into which the patients are moved immediately after implantation of their pacemaker contains ten (10) beds, each with American Optical hardwire monitors and is equipped with three (3) portable defibrillators and four (4) external pacemakers.
6. Description of applicant's present pacemaker implantation and follow-up program:



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The Medical and Dental Staff

Approximately 150 pacemakers have been implanted at North Kansas City Memorial Hospital since 1965 and 50 patients are being followed at the present time. For nuclear pacemakers, capture and sensing thresholds are measured from the implanted electrodes prior to attachment to the pacemaker and the programmable Nuclear Omni-Stanisor Pacemaker is set accordingly. At a minimum, EKG's are taken at implantation, 24 hours post implantation and one week post implantation. The Registration and Implant Data Form (Form 1, page B-2 of Protocol) will be completed and returned to Cordis Corporation within 10 days after implantation.

7. Methods applicant will establish to maintain records of implantation and follow-up of patients separate from routine hospital records: All nuclear pacemakers will be followed by both the implanting surgeon and the referring Internal Medicine specialist. At monthly intervals during the first six months and at three month intervals between semi-annual follow-up examinations, the performance of each pacemaker will be determined either by telephone monitoring or by a visit to the physician's office. Each follow-up examination or pacemaker performance determination will obtain the data on Form 2, page B-5 of the protocol, and a copy of the form will be returned to Cordis Corporation.
8. All nuclear pacemakers received by North Kansas City Memorial Hospital will be delivered immediately upon receipt to Mrs. Mildred Thiel, Operating Room Supervisor, who will maintain records, by serial number, of the receipt and use of each pacemaker and will securely store all such pacemakers under lock and key until they are delivered to Radiology or the Operating Room immediately before implantation. All activities involved in the receipt and use of nuclear pacemakers will be conducted in accordance with the regulations under Title 10, Code of Federal Regulations, Part 70.
9. The telephone operators of North Kansas City Memorial Hospital will be given instructions, copy attached, about receiving reports or inquiries about nuclear pacemakers, the information to obtain and the immediate reporting of such information to the appropriate physician(s).
10. The physicians responsible for the study confirm that they are familiar with the Cordis protocol referenced in Section 3 above and with the Cordis Nuclear Omni-Stanisor #184 pacemaker and they understand that the issuance of a license is conditioned upon the following of this protocol.
11. North Kansas City Memorial Hospital and the undersigned physicians agree to continue the follow-up, reporting and recovery



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The Medical and Dental Staff

procedures as long as the nuclear pacemaker is in a patient and until the pacemaker is recovered and returned to Cordis Corporation. In the event that one or more of the physicians named in this application are no longer associated with North Kansas City Memorial Hospital, the hospital will designate other qualified physicians to carry out these responsibilities under the license.

12. North Kansas City Memorial Hospital will follow instructions furnished by Cordis Corporation for packaging, labeling and shipping nuclear pacemakers for return and disposal.
13. North Kansas City Memorial Hospital hereby requests a license to receive, possess, store and implant the Cordis Omni-Stanacor #184 nuclear powered pacemaker in accordance with this application.

North Kansas City Memorial Hospital

By James E. Ferguson

Robert D. Williams, M.D.

Comer Bates, M.D.

Larry E. Benson, M.D.

Bryan T. Bownik, M.D.

Robert H. Hodge, M.D.

Newton C. McCluggage, M.D.

William R. Prather, M.D.





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## INSTRUCTIONS FOR TELEPHONE OPERATORS CONCERNING NUCLEAR PACEMAKERS

1. Accept any collect call with reference to "A Nuclear (or Radioactive) Pacemaker."
2. Any call concerning a radioactive pacemaker requires immediate action in order to avoid danger of radiation exposure and to ensure recovery of the radioactive pacemaker.
3. Obtain as much information from the caller as is possible including:

Caller's name \_\_\_\_\_

Where he may be reached (caller's address) \_\_\_\_\_

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

Patient's name \_\_\_\_\_

Where he may be reached (patient's address) \_\_\_\_\_

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

(Information from patient I.D. card)

Physician's name \_\_\_\_\_

Patient's address \_\_\_\_\_

Patient's telephone no. \_\_\_\_\_

Social Security no. \_\_\_\_\_

Pacemaker Type: Cordis Nuclear Omni- \_\_\_\_\_

Serial no. \_\_\_\_\_

Date of implantation \_\_\_\_\_

4. Notify immediately:

(1) Dr. Robert D. Williams at (816) 333-9332

If he cannot be reached:

(2) Notify immediately one of the following physicians:

Dr. Larry E. Benson at (816) 421-4240

Dr. Comer Bates at (816) 421-4240



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The Medical and Dental Staff

Dr. Bryan T. Bownik at (816) 421-4240  
Dr. Newton C. McCluggage at (816) 421-4240  
Dr. Robert H. Hodge at (816) 474-9232  
Dr. William R. Prather at (816) 474-9232

(The patient's attending physician and/or physician-on-call should take priority)

If 1 or 2 above cannot be reached:

Contact a physician on duty in the Coronary Care Unit or the Nursing Senior Team Leader in the Coronary Care Unit. Inform the individual contacted that the call involves a nuclear pacemaker and advise of the information received above and of the urgency of the matter.

If one of the physicians listed in 1 or 2 above was not contacted, one of them should be contacted as soon as possible and report the information.