



# Regulatory Docket File

70-2580

VETERANS ADMINISTRATION  
HOSPITAL  
3200 VINE STREET  
CINCINNATI, OHIO 45220

May 19, 1978

IN REPLY  
REFER TO: 539-112

Ms. Patricia C. Vacca  
Materials Branch  
Division of Fuel Cycle and  
Materials Safety  
U. S. Nuclear Regulatory Commission  
Washington, D. C. 20555

Dear Ms. Vacca,

RE: Application for license amendment to participate in a research study involving the implantation of Coratomic C-101 Isotopic Powered Pacemakers, each containing 250 milligrams of Pu-238 (4.3 curies).

1. The Veterans Administration Hospital hereby requests an amendment to its Special Nuclear Materials License No. SNM-1735 to implant a maximum of six Coratomic C-101 Isotopic Pacemakers annually during the study.
2. The Veterans Administration Hospital agrees to follow the Protocol on file at the Division of Fuel Cycle and Materials Safety entitled, "Human Clinical Protocol for the Coratomic C-101 Radioisotope Powered Cardiac Pacers", dated November 1, 1975. Copies of this Protocol have been provided to the above institutions and are on file at that institution.
3. Doctors Darryl J. Sutorius, James A. Helmsworth, J. Tracy Schreiber, and Harold Settle will be participating in this study. These physicians being included in the Veterans Administration Hospital Special Nuclear Materials License No. SNM-1735 presently in effect.

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REG3 LIC70  
SNM-1735

PDR

*William E. Claypool*  
Veterans Administration Hospital  
by: WILLIAM E. CLAYPOOL  
Hospital Director

Physicians Responsible for Study:

*Darryl J. Sutorius M.D.*  
DARRYL J. SUTORIUS, M.D.

*J. Tracy Schreiber M.D.*  
J. TRACY SCHREIBER, M.D.

*James A. Helmsworth*  
JAMES A. HELMSWORTH, M.D.

*Harold Settle M.D.*  
HAROLD SETTLE, M.D.

09441

FEE EXEMPT

"To care for him who shall have borne the battle, and for his widow, and his orphan."—ABRAHAM LINCOLN

(470)(a)(5)

*As per telcon  
6-6-78 w/  
Helen  
Mitsakou  
re approval  
letter  
to Smith  
6-6-78  
Mitsakou  
Ms. Royce  
Coratomic  
will send  
letter  
selection  
6-6-78*