Rec'd 9/13/91

Biocontrol Technology, Inc.

300 Indian Springs Road
P.O. Box 434
Indiana, Pennsylvania 15701
Telephone: (412) 349-1811
Fax: (412) 349-8610

NR-236-D-101-S

September 10, 1991

Mr. Stephen Baggett
U. S. Nuclear Regulatory Commission
Mail Stop 6H3
Washington, DC 20555

Dear Mr. Baggett:

RE: NR0236D101S

The above registration number was for the Coratomic Model C-100 pacemaker. We no longer manufacture this model. There were 93 pacemakers of this model implanted. We are hereby requesting that the registration for the Coratomic C-100 pacemaker be allowed to lapse, since we do not plan to manufacture any more Coratomic model C-100 pacemakers.

Sincerely,

John R. Klingensmith

John R. Klingensmith
Patient Records Specialist

U. S. NUCLEAR REGULATORY COMMISSION
FY 91 Annual Materials Fee Invoice
10 CFR 171.16

Invoice Date	Invoice Number
08/09/1991	AM02388-91

CORATOMICS, INC.
ATTENTION: RADIATION SAFETY OFFICER
BOX 434
INDIANA PA 15701

***** Mark THIS COPY with any billing address changes *****

License Number	Code AA905	Annual Fee Category(s)	Fee Amount	Surcharge Amount
NR0236D101S	ANN	9A	$ 6,100.00	$ 100.00
		TOTAL:	$ 6,100.00	$ 100.00
		TOTAL INVOICE:	$ 6,200.00	

Make Checks Payable To:
U.S. Nuclear Regulatory Commission <=== This PO Box address is
License Fee & Debt Collection Branch <=== for receipt of payments
PO Box 954514 <=== only.
St. Louis, MO 63195-4514

Terms and conditions are attached. Nonpayment of your annual fee may result in the revocation of your license(s) in accordance with the enforcement provisions of 10CFR171.23 of the Commission's regulations.

****
* *
* PAYMENT COPY *
* *
****

===> To ensure accurate credit, return this copy of the <===
===> invoice with your payment. Processing may be <===
===> delayed if the invoice is not included. <===

Biocontrol Technology, Inc.

P.O. Box 434 • Indiana, Pennsylvania 15701

Mr. Stephen Baggett
U. S. Nuclear Regulatory Commission
Mail Stop 6H3
Washington, DC 20555

SOURCE AND DEVICE EVALUATION TECHNICAL ASSISTANCE REQUEST

TO: STEVEN BAGGETT, NMSS/IMNS, Mail Stop OWFN-6H3

FROM: Bio Control Technology 300 Indian Spring Rd REGION: I II III IV V HQ (Circle One)

FTS PHONE NO. P.O. Box 434 Indiana PA 15701 DATE: _____

APPLICANT _____ LETTER/APPLICATION DATE 9/10/91

MAIL CONTROL NO.(S) ✓ LICENSE NO.(S) _____

REQUEST ACTION (CHECK APPROPRIATE BOX)

( ) SOURCE REVIEW ( ) DEVICE REVIEW ( ) CUSTOM

( ) AMENDMENT OF REGISTTRATION SHEET NO. _____

( ) OTHER: _____

****

FOR NMSS/IMAB USE ONLY CONTROL NO. 91 - 126 MODELS: 400

DATE RECEIVED 9/13/91 REVIEWER _____

TYPE OF ACTION (INDICATE NO. OF EACH ON THE LINES)

( ) SOURCE REVIEW ____ (X) DEVICE REVIEW 1

( ) FORMAL (X) AMENDMENT ( ) CUSTOM Fee Rule

( ) NO LICENSING ACTION REQUIRED

TOTAL REVIEWER HOURS SPENT ON EVALUATION ____ DATE COMPLETED _____

NOTES: _____ DEFICIENCY LETTER ____ DATE COMPLETED _____

DEFICIENCY PHONE CALL ____ DATE MADE _____

RESPONSE TO DEFICIENCY _____

TYPING DRAFT __ IN __ OUT __ FINAL __ IN __ OUT __

****

FOR ARM/LFMB USE ONLY

FEES THAT HAVE BEEN PAID FOR : (INDICATE NO. OF EACH ACTION ON THE LINES)

( ) SOURCE REVIEW ____ ( ) DEVICE REVIEW ____ ( ) FORMAL ____

( ) AMENDMENT ____ ( ) ARM/LFMB ____ ( ) CUSTOM ____

NOTES: _____ DATE TO ARM/LFMB: _____

DATE RETURNED: _____

SIGNED: _____

DATE: _____

INDIVIDUAL SSD CASE STATUS

ASSIGNED #: _____
REVIEWER: _____
DATE ASSIGNED: _____
MAIL CONTROL #: _____

MANUFACTURER: _____
MODEL #: _____
CONTACT: _____
PHONE NUMBER: _____

FOR THE FOLLOWING, ENTER DATE OF COMPLETION, OR EXPLAIN DEFICIENCIES.

	DATE	EXPLANATION
PAGE HEADING:		
COVER PAGE:		
DESCRIPTION:		
LABELING:		
DIAGRAM:		
CONDITIONS:		
PROTOTYPE TESTING:		
EXT. RAD. LEVELS:		
QA/QC:		
LIMITATIONS:		
SAFETY ANALYSIS:		
REFERENCES:		

	PHONE	LETTER
DEFICIENCY 1:		
DEFICIENCY 2:		
DEFICIENCY 3:		
DEFICIENCY 4:		

SPELL CHECK: _____
1ST. DRAFT: _____
2ND. DRAFT: _____
COMPLETED: _____
COMP. LETTER: _____

SSD CASE STATUS

MANUFACTURER:_____

MODEL#:_____

REFERENCES:_____

	DESCRIPTION	DATE REVIEWED	OK/DEF	DATE DEF RESP COM	DATE COMP
(1)	Registrant's Name and Address				
(2)	Manufacturer's Name and Address				
(3)	Custom User's Name and Address				
(4)	Device Model Number				
(5)	Device Type				
(6)	User's Authority to Possess (specific, general, exempt)				
(7)	Radionuclides, Activity (Max. w/%error) Form, Manufacturer, Model, NRC registered.				
DESCRIPTION					
(8)	Device Design with Complete Engineering Drawings (dimensions, tolerances, list of materials)				
(9)	Assembly methods (screws, welds, etc.)				
(10)	Source Mounting (size and integrity) and Security. ANSI Classification (43232 for gamma gauges)				
(11)	Shutter Operation				
(12)	On-Off Indicator (lock in Off, not in On)				
(13)	Safety interlocks, guards, etc. to prevent access to beam or high radiation levels.				
	Depleted Uranium (on label) Corrosion with steel (copper/zinc)				

	DESCRIPTION	DATE REVIEWED	OK/DEF	DATE DEF RESP COM	DATE COMP
	Steel and Aluminum (Corrosion)				
	Source for well-logging (nondispersible)				
RADIATION PROFILES					
(14)	Survey Instrument used (type, window, cali., sensitivity)				
(15)	Conditions				
(16)	Nuclide and Activity (Maximum allowable?)				
(17)	Distance form Source, Surface				
(18)	Shutter On and Off				
(19)	Source Shielded				
(20)	Scatterer (product) in Beam				
(21)	Guards and Shields in place				
INSTALLATION					
(22)	Fixed, Portable, Movable, Fixed installation but movable source housing.				
(23)	Inherent shielding, inaccessibility				
(24)	Interlocks, locks, barriers				
(25)	Beam Access; size of gap and opening to beam.				
(26)	Mounting integrity				
PROTOTYPE TESTING					
(27)	Tests methods and conditions (ANSI, ISO)				
(28)	Tests Results				
(30)	Years of Use (incidents, failures)				

	DESCRIPTION	DATE REVIEWED	OK/DEF	DATE DEF RESP COM	DATE COMP
QUALITY CONTROL					
(31)	Materials, subassemblies				
(32)	Assembly methods (welds, screws, etc.)				
(33)	Dimensions tolerances				
(34)	Activity, Radiation levels, and leak/contamination				
(35)	Quality Assurance Manual				
LABELING					
(36)	Copy of the label				
(37)	Contents (model#, serial#, trefoil, activity, logo, isotope, "CAUTION-RADIOACTIVE MATERIAL", date of assay)				
(38)	Material				
(39)	Dimensions				
(40)	Colors				
(41)	Attachment (permanent)				
(42)	Location				
SAFETY INSTRUCTIONS					
(43)	Operation, Maintenance, Calibration, Damage/failure, Specific warnings, leak test, and radiation profile checks.				
ACCOMPANYING DOCUMENTATION					
(44)	Results of leak test and radiation surveys.				
(45)	Transportation documents				
(46)	The Above Instructions (if user performs operation)				

DESCRIPTION	DATE REVIEWED	OK/DEF	DATE DEF RESP COM	DATE COMP
SERVICING				
(47) Manufacturer or user performs: ____Installation ____Relocation ____Maintenance ____Repair ____Source install/reinstall ____Calibration ____Leak Testing ____Radiation Survey ____Training	_____	_____	_____	_____
Foreign Manufacturers				
Drop ship				
Where is source installed and who installs it.				
Wipe test/rad survey.				
QA in this country.				

JUPITER TECHNICAL REPORT

CORATOMIC/BIOCONTROL TECHNOLOGY PACEMAKERS

General

This review concerns the Coratomic Model C-100 pacemaker, assign #91-126 and its successor models. This is the first of a series of pacemaker designs, and was developed in 1972 and 1973, according to page 2 of the Coratomic Inc. letter of June 24, 1980. The first two implants of the C-100 occurred on October 3, 1974 under license SNM-1319. These each accumulated implant times of 64.9 months by the time of the letter.

This pacer was modified by widening its bandpass in the spring of 1975 so it would sense a larger number of patient's R-waves. The Model number was changed to C-101, and implants continued under a Human Clinical Protocol issued November 1, 1975. It far exceeded the objectives established by NRC for its implantation. It achieved a level of reliability three times higher than anticipated and twice that of the control group of conventional pacers established for the C-100 series in 1974.

The Model C-101-P pacemaker is "essentially equivalent" to the Model C-101 implanted prior to May 28, 1976, according to the Coratomic letter of June 24, 1980. The isotopic battery used in the C-101-P is identical to that used in the C-101. It uses the electronics from the Ovalith-P (a lithium-battery powered pacemaker), and the case of the L-500 (also a lithium-battery powered pacemaker). The C-101, Ovalith-P, and L-500 pacemakers were all in use or judged "essentially equivalent" to pacemakers implanted prior to May 28, 1976. This information is contained in the Coratomic, Inc. letter of June 24, 1980. On the basis of this, it appears they never had the C-101 or C-101-P models registered, but they need to be closed out by a termination applicable to all three models. Termination of the Model C-100 is requested in the Biocontrol Technology, Inc. letter of September 10, 1991, without mention of the other models, since they were never registered in the first place.

All three of these models, as well as the Pulsar-N1, were licensed in Amendment 22 to license #1319 on November 1, 1988. It therefore seems appropriate to terminate them all in one action, since the newer models were never registered.

DESCRIPTION

The description of the power source in the original registry was complete and accurate, so it was utilized as much as possible. However, there was no description of the outer package, nor of the other models, so it was necessary to add material to address these factors. There are no drawings of the power source in the reference material, or even of its location in the devices, since this was apparently considered too proprietary to include in the files. However, other diagrams were found, as explained below.

The overall dimensions provided in the registry are taken from the proprietary drawings in the file. For the Model C-101, similar dimensions are also found on page 15 of the Physician's Technical Manual. For the Model C-101-P, they may be found on page 10 of the Physician's Technical Manual. No dimensions were found for the Pulsar-N1 device.

DIAGRAMS

All the drawings are stamped "proprietary." However, the original registry had a diagram for the original Model C-100 device which we have used again as Attachment 1. There was also a photo of the label and the device in a technical manual for the Model C-101, which is utilized as Attachment 2. The photo in the manual for the C-101-P was not clear enough to use, but appeared to have similar label contents. A copy of the radioactive patient identification card provided by Coratomic, Inc. is shown on page 10 of the Human Clinical Protocol dated November 1, 1975. This is one form of label for the device.

EXTERNAL RADIATION LEVELS:

This information was all copied from the original registry, since no such iformation was fund in the files.

QUALITY ASSURANCE AND CONTROL

This topic is not discussed in the original registry. Coratomic, Inc. makes many claims regarding the high quality of their program for their circuits, but are less specific about the isotopic battery. They state on pages 6 and 10 of the Physician's Technical Manuals that the total failure rate of battery components is calculated to be 0.15% per year. They also state that thermoelectric modules have been on test for 4 years with no degradation. Coratomic states in these same manuals that they test all incoming components individually as they are received, while all in-process components are tested at each critical assemply and/or fabrication state.

On this basis, a standard paragraph, which assumes the Coratomic plan was approved by NRC, was used.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

The first paragraph is copied from the original register. The others are standard for terminations.

QUALITY ASSURANCE AND CONTROL

A brief statement about the Coratomic plan is made. This is followed by a standard paragraph used when information is not complete.

LIMITATIONS AND/OR OTHER CONSDERATIONS OF USE

The statement in the original register is used, followed by appropriate standard paragraphs for terminations.

SAFETY ANALYSIS SUMMARY:

Standard paragraphs were used, since no information was available.

References ——→ ?