70-1342
RETURN TO
D. CRAWFORD
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Coratomic
P.O. BOX 434, INDIANA, PENNSYLVANIA 15701
PHONE (412) 349-1811 TELEX 86-6658

June 3, 1981

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

Dear Mrs. Vacca:

Coratomic, Inc. is requesting a temporary amendment change to our special nuclear material license, SNM 1319, for the shipment of two C101-P pacemakers, Serial Numbers 1156 and 1157, to Ken Williams at Washington Hospital Center, Ref. SNM-1446. Mr. Rahmoeller fo the FDA has given verbal approval to implant the above pacemakers under the custom device law with shipments of all other C101-P's being halted until approval from FDA and NRC.

See the enclosed sheet for specifications on Coratomic, Inc. model C101-P vs Cordis Corporation model Omni-Stanicor. Coratomic's model is more desirable for long-term implant due to the wider range of programmability. It should also be noted that the C101-P also has a weight and size advantage over other isotopic pacemakers.

It is for humanitarian reasons that we are requesting that the NRC react on the license amendment change. Enclosed is the amendment fee of $464. Doctor Nicholas P. D. Smyth, M.D. has requested two C101-P pacemakers as custom devices for implant in patients requiring this device. Please co-ordinate our amendment change with Washington Hospital Center change for all requested information.

Coratomic, Inc. regrets any misunderstanding between the three parties, the FDA, NRC and Coratomic. We were under the impression the NRC and FDA were in agreement on the implants. We hope that NRC, FDA and Coratomic, Inc. can work together with more clarity in the future.

Sincerely,

David Kallas

David Kallas
Quality Control

DK:pck

enclosures

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Rfd 24 $464 (10A) June PG 10 Amend.

Applicant 9102 $464 Amendment
Check No.
Amount/Fee Category
Type of Fee
Date Check Rec'd 6/12/81
By Brown

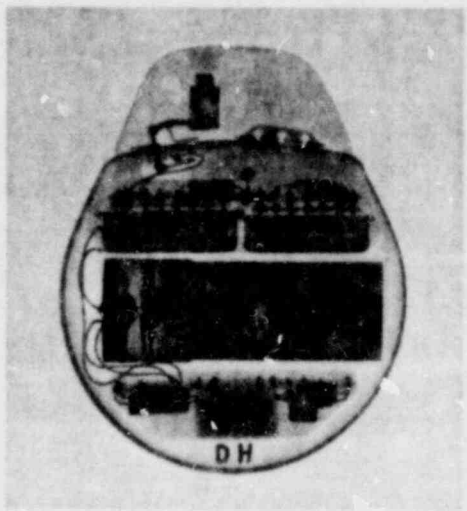
Log By Brown
Orig. To
Action Compl. 6/15/81

8107220180 810603
PDR ADOCK 07001342
C PDR

Omni-Stanicor® ν (Nu)

Nuclear-Powered, Programmable, R-Wave Inhibited (VVI) Cardiac Pacer

Model 184A or Model 184B
Catalog No. 307-305



Specifications

(at 37°C and time of manufacture)

	Nominal	Range
Output current*, mA (as programmed)	8 (High)	7-10
	5 (Med)	4-7
	3.5 (Low)	3-5
	2.0 (Test)	1.5-3.0
Fixed rate, ppm (as programmed)	60	58-64
	65	63-69
	70	68-74
	80	78-85
	90	88-97
	100	98-108
Output voltage, V (open circuit)	6.0	5.9-6.1
Sensitivity† (+ or −), mV	1.5	1.0-2.0
Pulse duration‡, ms (at 70 ppm)	1.7	1.6-1.8
Refractory‡, ms (at 70 ppm)	311	289-326
Weight	90 grams	
Size	56 × 68 × 20 mm	
Specific gravity	1.80	
Radiopaque identification letters	DH (Model 184A) PJ (Model 184B)	

*Measured into a 510-ohm load and sampled 0.2 ms after the start of the pulse.

†Measured with a rectangular voltage step. Sensitivity varies significantly with the rate at which the input signal rises and the duration of the rising voltage.

‡Varies with rate. See the instructions supplied with the pacer.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Prior to implantation, read the instructions supplied with the pacer.

Cordis Corporation
P.O. Box 370428
Miami, Fla. 33137, U.S.A.
Telephone 305-578-2000

cordis.

DIMENSIONS & SPECIFICATIONS - C-101-P Programmable Isotopic

Weight	61 gm
Max. Thickness	1.9 cm
Height	5.1 cm
Length	6.4 cm
Specific Gravity ..	1.56 gm/cc
Longevity	At 40-45 years, a rate drop of approx. 10% will begin. The transition to the 10% decrease will take approx. 3 years. After the 3-years, the rate will remain relatively constant for another 30 years.
Pacing Rate	Programmable @ 38 to 120 ppm 13 rates
Pulse Current	Programmable @ 4 and 10 ma (leading edge, BOL)
Sensitivity	Programmable @ 1.5, 2.5, 4.0, 5.0 mv
Pulse Width	1.0 ± 0.1 msec @ BOL (increases to 1.4 msec @ EOL)
Pulse Voltage	5.4 v, nominal @ 10.6 ma
Escape Rate	Same as programmed pacing rate
Magnetic Rate	Same as programmed pacing rate
Noise Rate Threshold	< 25 hz (will switch to an asynchronous mode at the programmed rate when continuous electromagnetic interference is encountered at or above its noise threshold)

Normally used as an R-wave inhibited (VVI) pacemaker.

Asynchronous (V00) pacing can be obtained by placing the SENSITIVITY selector to its FR (Fixed Rate) setting.

Available only in unipolar design (at this time)

Hermitically sealed in a titanium case.

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