If this seal is broken, Guidant will not accept contents for credit or restock.

CONTAK RENEWAL® 3 RF
Model: H210 IS-1/IS-1/DF-1
Serial 999999
Use Before 01 JAN 2000

Preliminary Draft

CONTAK RENEWAL® 3 RF

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

Model: H210

Connectors:
IS-1 Pace/Sense (LV)
IS-1 Bipolar Pace/Sense (A and RV)
DF-1 Defibrillation

CONTENTS: pulse generator, torque wrench, literature, and patient data disk

CAUTION: DO NOT STORE NEAR MAGNETS OR MAGNETIC DEVICES.

CAUTION: Knowledge of the enclosed literature is essential for the proper use of this device. Recommended storage temperature range is 0°C to 50°C.

CONTENTS HAVE BEEN STERILIZED with gaseous ethylene oxide.

CAUTION: Federal law (USA) restricts this device to sale, distribution, and use by, or on the lawful order of a physician trained or experienced in ICD implant and follow-up procedures.

Note: For important information regarding clinical evaluation of this device, please see the Clinical Summary in the CRT-D System Guide.

Serial 999999
Use Before 01 JAN 2000
Sterile Lot 999999

Bar Code

Bar Code

CONTAK RENEWAL® 3 RF
Model: H210 IS-1/IS-1/DF-1
Serial 999999
Use Before 01 JAN 2000

Preset at Factory at 37°C and 500 Ω load

Tachy Mode	Storage
Number of Zones	1
VF Rate	165 bpm
Shock Energy Stored	31 J
Waveform	Biphasic
Antitachycardia Pacing	Off
Type	DDDR
Heart Failure/ Brady Mode	DDD
Heart Failure/ Brady Rate	40 ppm
Pacing Chamber	Biventricular
Pulse Amplitude	3.5 V
Pulse Width	0.4 ms
Monitoring Voltage	> 3.0 V

All therapy counters preset to zero.

H210US1 11/14/03

13209-001 A
FCC ID: ESCCRMH21004

-----Original Message-----
From: Raymond Laforge [mailto:RLAFORGE@fcc.gov]
Sent: Monday, September 29, 2003 2:05 PM
To: Schneider, Joel
Subject: Re: urgent labeling question

Reply * Yes, the alternative FCC ID labeling scheme for implanted transmitters that is proposed by your client is acceptable to the Commission.

>>> Schneider, Joel 09/23/03 05:10PM >>>
I'm sure everything is urgent, but the customer would like OK on attached labeling proposal in order to proceed with mfg. process. Thanks in advance.
<<guidant label.doc>>

ORIGINAL REQUEST FOLLOWS

19 September 2003

FCC
Office of Engineering and Technology

To Whom It May Concern:

Re: labeling of implantable devices

My name is Joel Schneider, senior engineer with TUV America, a NVLAP accredited EMC test lab in MN. I have been authorized by one of our customers, Guidant Corporation, to address the labeling issue of an upcoming type of product for them. Guidant is a world leader in the design and development of cardiovascular medical products, whose devices help patients with heart disease return to active and productive lives. They provide physicians with leading-edge technologies for improved patient management and clinical outcomes. They will be submitting for certification 10-15 RF products - implantable devices that will go in the human body, and will incorporate Part 15 transmitters for programming/monitoring. These devices are 1-4 inches maximum dimension. Due to the size of the devices, and the end use, Guidant wishes to put the FCC ID: somewhere else, rather than on the unit itself.

47 CFR 2.925(f) states that "Where it is shown that a permanently affixed nameplate is not desirable or is not feasible, an alternative method of positively identifying the equipment may be used if approved by the Commission. The proposed alternative method of identification and the justification for its use must be included with the application for equipment authorization.

Note: As an example, a device intended to be implanted within the body of a test animal or person would probably require an alternate method of identification."

In line with this, Guidant proposes putting the FCC ID: label at the following locations:

* Systems Guide – this goes to the surgeon who will implant the device.
* Box label – this will be thrown away after the implant is taken out of the box.
* Physician's technical manual – this is something the patient's physician will keep.
* Patient's ID card – this will be given to the patient to keep in his wallet.

All of the other information required to be on the label will be inserted in the manuals, which is generally allowed for small products. Guidant would like to ensure this labelling strategy is acceptable to the FCC prior to implementing it into their production plans.

Thanks in advance. If you need clarification on any issues, or if you have further questions, you can contact me at 651 638 0297, or jschneider@tuvam.com.

Sincerely

Joel T Schneider
Senior Engineer
TUV America – Minnesota OATS