BIOTRONIK

BIOTRONIK GmbH & Co. KG • Postfach 47 02 55 • 12311 Berlin

Federal Communications Commission
Equipment Authorization Branch
7435 Oakland Mills Road
Columbia, MD 21046
USA

Berlin, December 05, 2006

Re: Request For Confidentiality
BIOTRONIK GmbH & Co. KG
FCC ID: QRILUMAXT
FCC Certification

Gentlemen,

In accordance with 0.459 of CFR 47, BIOTRONIK GmbH & Co. KG hereby requests confidentiality of the following documents:

Exhibit Type	Description	File Name
• Block Diagram	BlkDia	LUMAXT BlkDia.pdf
• Operational Description	Antennainfo	LUMAXT AntSpec.pdf
• Schematics	Schem	LUMAXT Schem.pdf
• Internal Photos	Photos, IntPho rev1	LUMAXT IntPho.pdf; LUMAXT IntPho rev1.pdf
• Operational Description	OpDes	LUMAXT OpDes.pdf
• Part List / Tune Up Info	PartsList	LUMAXT PartsLst.pdf

included as attachments for the subject application.

The reasons for requesting confidentiality of these items are that this transmitter circuitry and its performance are BIOTRONIK proprietary designs.

- If disclosed, this information would result in substantial competitive harm. Utilizing the current new generation bi-directional RF communications in ICD´s is a novel approach, which BIOTORNIK seeks to exploit as a competitive advantage.
- Design and development efforts were substantial, and if such information are provided to competitors would create an unfair market advantage to those gaining the information
- BIOTRONIK feels that this feature will provide first-to market advantage that will provide financial gains of millions of dollars. These gains would be greatly diminished if such proprietary information was made publicly available to competitors.
- The internal photos will also reveal information about non-radio design elements that are also BIOTRONIK proprietary design and if disclosed could result in substantial competitive harm.
- Note: The Lumax devices are implantable cardioverter / defibrillators. These devices are not allowed (by law) to be sold in a store or pharmacy to the public. Therefore it is not possible to buy such a device in a public store. A BIOTRONIK representative usually participates during the operation and in most cases brings the device with him to the operation. Until operation/implantation the device is stored in a non resealable semi-opaque sterile container. Any damage of the container before implantation would be noticed and the device could not be used

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for implantation any longer. The housing of the device itself is made of titanium and fully laser welded. It is not possible to open the device without destroying it. Therefore before implantation it is impossible that somebody outside BIOTRONIK personnel has the opportunity to open the device in order to get the information BIOTRONIK requests to be held confidential .
After implantation the device can only be removed from the patient by an operation in a hospital and replacement of the device.
The user manual includes a X-ray picture. This is required by international standards. The device is quipped with a X-ray identification (HR and the year of manufacture) in order to identify the type of the device and manufacturer without the need to carry out an invasive procedure. This X-ray picture does not show detailed information of the inner assembly since it is only a two dimensional figure. Because of the nature of X-ray pictures, it does not show all used materials/parts and details.

If there are any further questions regarding the BIOTORNIK request for confidentiality, please contact Gunnar Boersch at + 49 30689051213 or gunnar.boersch@biotronik.com.

Sincerely

Gunnar Boersch
Manager Regulatory Affairs