

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

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

Berlin, 2006-11-03

Re: Statement to the FCC ID:

FCC ID: QRILUMAXT Labeling Scheme

Per 47 CFR 2.926 (e),

"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."

Since the EUT is implanted in the human body and packed before implantation in an opaque sterile box that can not be opened before implantation in order to maintain the sterile condition of the device, the FCC ID will not be applied to outside of the device since it would not be visible prior and after implantation.

Instead, the applicant is proposing the following alternate method of applying the FCC ID number to two locations:

1. The FCC ID labeling information page which includes the FCC ID is provided on page 149 of 152 of the pdf file (or page 147 of the document pagination) in the user's manual submitted with the filing.
2. The FCC ID also appears on the package label, which is affixed to outside of the shipping box for the Lumax devices.

Sincerely



Gunnar Boersch
Manager Regulatory Affairs