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Equipment Authorization Branch
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Berlin, March 27, 2008

Application for Class II permissive Change FCC ID QRI LUMAXT

Dear Madam or Sir,

BIOTRONIK GmbH & Co. KG herein seeks Class II permissive Change of its above referenced equipment authorization for the purpose of adding 8 additional variants to the already approved devices.

The new variants

Lumax 500 VR-T	order number #360344
Lumax 500 VR-T	order number #360345
Lumax 540 VR-T	order number #360348
Lumax 500 DR-T	order number #360340
Lumax 500 DR-T	order number #360341
Lumax 540 DR-T	order number #360346
Lumax 500 HF-T	order number #360342
Lumax 540 HF-T	order number #360347

uses a modified firmware in order to support additional therapeutic / diagnostic features and a modification of the shock path in the circuit layout.

To implement a non-active housing shock path for 'Lumax 500/540' the HSK 4130 was developed. HSK 4120 is a derivative of HSK 4130, used for the current distributed Lumax devices. HSK 4130 consists of the same ICs and components as HSK 4120, also the principal layout of the hybrid is unchanged but a third high voltage channel HV-3 with separate multichip module and pulse transformer has been added. Furthermore to allow lead impedance measurements via HV-3 an additional protection transistor, a Zener diode array and some additional capacitors have been added on HSK 4130.

However, the RF transceiver module including layout and location of the hybrid and the antenna remains unchanged. Therefore the radio device characteristics are unchanged of the Lumax 500/540 compared to the currently distributed Lumax 300/340 devices.

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Batteries

The power supply of all Lumax ICDs are 3V batteries. In 'Lumax 300/340' either the Greatbatch 'GB 2491' battery with Li/SVO/CFx chemistry or the Litronik 'LiS 3182 K7' (Li/MnO₂) battery are used. For 'Lumax 500/540' also the 'GB 2491' or alternatively the Litronik batteries 'LiS 3182 R6' or LiS3192 R7' are used.

The 3V batteries 'LiS 3182 R6' and 'LiS3192 R7' are a further developments of the 'LiS 3182 K7' used in 'Lumax 300/340'. All these Litronik batteries are based on Li / MnO₂ chemistry. The capacity of the new 'LiS 3182 R6' and 'LiS 3192 R7' is about 14% , 40%, respectively; higher than those of 'LiS 3182 K7'.

The open circuit voltage and the cut off voltage (lowest voltage by what the ICD will activate the CPU or Transceiver) are unchanged.

Therefore the transmitter parameter are not affected by the use of the new batteries.

The documents LUMAXT_OpDes, LUMAXT_TestRpt, LUMAXT_RFExp, LUMAXT_TestRpt1, LUMAXT_TestRpt2 1, LUMAXT_TestRpt2 2 are still valid for the additional variants.

Sincerely yours,
BIOTRONIK GmbH & Co. KG

A handwritten signature in black ink, appearing to read 'G. Boersch', written over the printed name.

Gunnar Boersch
Team Manager Regulatory Affairs