ST. JUDE MEDICAL

October 27, 2006

ELECTRONIC SUBMISSION

Marlene H. Dortch, Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: ET Docket No. 06-135
RM-11271

Comments to:

NOTICE OF PROPOSED RULEMAKING
NOTICE OF INQUIRY
AND ORDER

Dear Ms. Dortch,

St. Jude Medical welcomes the FCC's efforts toward implementing rules to better accommodate communication between medical equipment specifically related to the bands:

- MEDS: 401 - 402; 405 - 406 MHz
- MICS: 402 – 405 MHz

We also welcome harmonization of frequency bands world wide. St. Jude Medical would however like to submit the following comments for your consideration:

Comment 1: In reference to Item 24 on page 10

St. Jude Medical strongly believes that an additional access method to the MICS band should be enabled. An ultra low duty cycle access (0.01%) that can be used by MICS implants only on the center channel: 403.5 – 403.8 MHz with limited output power:100 nW e.r.p, as an interference reduction technique for mutual in-band interference.

Rationale:
Patient safety has been recognized by the International Telecommunications Union – Radiocommunications (ITU-R) in Recommendation ITU-R SA 1346: "Clearly, it is vital patients suffer no harmful effects from interference". The ITU-R SA 1346 document also recommends "that interference mitigation techniques, as discussed in Annex 1, should be used by Medical Implant Communication Systems to protect their operation."

Presently the spectrum access requires Listening Before Talk and Adaptive Frequency Agility (LBT/AFA) before transmission. With the purpose to be consistent with the direction in which the European Telecommunications Standards Institute (ETSI) is moving, referring to published draft standard, St. Jude Medical proposes a slightly modified FCC regulation to access the MICS band in addition to the present LBT/AFA for the monitoring system before transmission.

LBT/AFA is not a technically suitable method for the implant to access the MICS band due to technical limitations.

The ultra low duty cycle access via the centre channel in the MICS band enables the implant to initiate communication with an external unit. It is essential that the ultra low duty cycle access only be allowed on one channel in the middle of the protected MICS band while minimizing risk of interference with other medical equipment. Due to the ultra low duty cycle and low output power, this change should not affect a robust RF system already operating according to the current release of the MICS standard. A typical application is monitoring of the patient at home where the implant can initiate communication whether there is an emergency situation or not.

The following advantages for the remote follow up application in relation to LBT can be seen:

- Allows device to initiate communication
- Simplified access method.
- Reduced timing synchronization requirements.
- Extended battery longevity for implanted device.
- Less complex radio design required for device
- Easier for patient since the device can initiate communication automatically without patient interaction.

Allowing the use of low duty cycle as an additional interference mitigation technique will allow medical device manufacturers to make use of these advantages.

St. Jude Medical believes that it is not acceptable to use the MEDS band for initiation of a MICS communication from the implant due to:

1. The middle channel in the MICS band is the most protected channel.
2. The ultra low duty cycle access will not interfere with MICS communication.
3. The MEDS band can be occupied with several other body worn transmitters
4. The ultra low duty cycle access within the MICS band is already on its way in Europe via ETSI published draft standard: Draft ETSI EN 301 839-1 V1.2.1 (2006-05)

The European MICS standards are the process including an ultra low duty cycle channel within the MICS band. The updated standards are expected to be published in February 2007.

Comment 2: In reference to Item 29 on page 12

St. Jude Medical does not support "providing the flexibility in the use of spectrum for implanted and body-worn medical radio devices."

It is also essential to ensure minimal spillover from MEDS channels to adjacent MICS channels, increasing the noise level, as both the MICS and MEDS system can be used simultaneously on the same patient**.**

Rationale:
It is essential that the MICS band provide the best conditions for downloading of therapeutic data to active implantable medical devices. It is thus essential that the MICS band only be assigned to such applications and not to general communication with, for example, body worn devices.

Comment 3: Item 47-48 on page 17

St. Jude Medical believes that the FCC should not be involved in judgments regarding the level of immunity of a medical electrical system.

Rationale:
St. Jude Medical believes that the most appropriate governmental agency to assure the safety of medical devices continues to be the Food and Drug Administration (FDA). Therefore, the assessment of medical devices specifically for electromagnetic compatibility should also continue to be under the purview of FDA who has the knowledge of the indented uses of these devices and has the technical competence to determine the medical risks and review the associated risk control mechanisms using global standards to guide their judgments.

Please direct any questions on this matter to the undersigned.

Respectfully Submitted,

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