

From: Rich Fabina [mailto:RFABINA@fcc.gov]
Sent: Friday, September 12, 2003 4:24 PM
To: Schneider, Joel
Subject: Re: implantable transmitters

Joel,

Implants under Part 15 may be granted but only by the Commission. A TCB is prohibited from granting one by the 02 TCB Exclusion List, II Portable Transmitters, c). Any Part 15 transmitter that meets the limits may be approved by the Commission even if it is implanted in a body.

I believe implants also require FDA approval. You might want to contact them for information on their approval process.

The second part of your question can only be answered on a case-by-case basis. If a transmitter is tested on an open area test site, it's power may be below a level where we become concerned about RF safety or SAR measurements. It all depends upon the frequency and usage. Implants tested in tissue must have a waiver or special permission to test in this manner since it is not permitted in ANSI C63.4 (1992/2001). Testing in tissue will attenuate the transmitted signal to power levels that may raise RF safety concerns with the Commission. Other than that I cannot give you any specifics without operating details of an individual transmitter.

I hope this is responsive to this inquiry.

Rich Fabina

-----[Joel T Schneider email]-----

t 15 and that Part 95 for MICS would be an option for the mfr, but it does not mandate that all implantable transmitters can only be certified under Part 95. The Medtronic submittals were done prior to the MICS allocation, so I would like to clarify that my interpretation of the rules is correct.

Secondly, most Part 15 transmitters require RF exposure evaluation, but do not require SAR testing. If the power level of the implants are low enough, is it true they would not require SAR testing? Or is there special consideration for devices in the body, or do they merely fall under the <20 cm guidelines.

Thanks in advance.

[Joel T Schneider
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