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July 17, 2008

Via Electronic Filing

Marlene H. Dortch, Secretary
Federal Communications Commission
445 12th Street SW
Washington, DC 20554

Re: *Ex Parte* Notice: *Investigation of the Spectrum Requirements for Advanced Medical Technologies* – ET Docket No. 06-135; *Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz* – RM-11271

Dear Ms. Dortch:

On July 16, 2008, Kimberley Elting and Ben Tranchina of Advanced Neuromodulation Systems, Inc. ("ANS"), and Stephen J. Berman and the undersigned, counsel for ANS, met with Julius Knapp, Ira Keltz, Geraldine Matise, Jamison Prime, Mark Settle, Alan Stillwell, and Gary Thayer of the FCC's Office of Engineering and Technology. During the meeting, the parties discussed the attached presentation regarding operation of partially implanted medical devices at 402-405 MHz under the Commission's proposed MedRadio rules.

As ANS noted during the meeting, allowing certain temporary body-worn transmitters to operate at 402-405 MHz (the core MICS band) would not implicate the concerns raised by some parties. For example, Medtronic has pointed out that "[w]hile implantable medical devices are limited to ultra low level transmissions by virtue of their battery constraints, body-worn devices are not so limited."[1] Given this perceived disparity, Medtronic has voiced concern that allowing all types of body-worn devices in the core band would interfere with the operation of implantable devices, forcing fully implanted devices to expend energy looking for an available channel or preventing them from finding

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[1] Reply Comments of Medtronic, Inc., ET Docket No. 06-135, RM-11271, at 21 (Dec. 4, 2006).

an available channel altogether.[2] While this concern may be well-founded for many body-worn transmitters, it is not warranted for the limited class of body-worn transmitters proposed by ANS to operate in the core band – *i.e.*, transmitters connected through the skin to a surgically implanted medical device. Those transmitters would be body-worn only for a short period of time in order to allow physicians and patients to evaluate the medical device prior to permanent implantation; would operate at a reduced measured field strength; would be subject to technical constraints (including listen-before-talk and frequency-agility requirements) that are identical to those that apply to implanted transmitters; would involve only infrequent communications and would not entail continuous streaming of data; and would otherwise comply with FCC requirements applicable to implanted transmitters.[3] As a result, these temporary body-worn transmitters would not expose implanted transmitters in the core band to intensified interference, nor would they cause implanted batteries to experience additional power drain. Medtronic's concerns thus are not applicable to the limited class of temporary body-worn transmitters described by ANS.

Pursuant to the Commission's rules, this letter is being submitted for inclusion in the public record of the above-referenced proceeding.

Sincerely,

/s/ Richard D. Mallen
Richard D. Mallen

cc: Ira Keltz
Julius Knapp
Geraldine Matise
Jamison Prime
Mark Settle
Alan Stillwell
Gary Thayer

Attachment

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2 *Id.* at 19-21.

3 *See* attached ANS presentation at 10.

MedRadio Proceeding: Permitting Partially Implanted Devices at 402-405 MHz

Presentation to OET Staff by

Advanced Neuromodulation Systems, Inc.
a St. Jude Medical Company

July 16, 2008

ANS
A St. Jude Medical Company

Company Overview

- Wholly-owned subsidiary of St. Jude Medical
- Located in Plano, Texas
- More than 900 employees
- Manufactures spinal cord stimulation ("SCS") systems that improve the quality of life for many people who suffer disabling pain or nervous system disorders

Spinal Cord Stimulation

- SCS systems are sometimes called "pacemakers for pain"
- An SCS system generates mild electrical pulses and sends them to the spinal cord through electrodes on thin cables implanted in the body, known as "leads"
- These pulses replace the feeling of pain with a tingling or massaging sensation
- Patients who use SCS devices may obtain significant relief from severe chronic pain that is otherwise untreatable

Advanced Technology

- SCS devices contain sophisticated hardware and software, reflecting years of research, development, and testing
- SCS devices must also be approved by the FDA
- These factors are reflected in the reimbursement rates for the implantation of an SCS system: more than $30,000 for Medicare

Robust Competition

- SCS market is highly competitive
- SCS devices are currently manufactured by three companies:
  - Medtronic
  - Boston Scientific
  - ANS/St. Jude Medical
- ANS is always looking to develop better products to serve patients

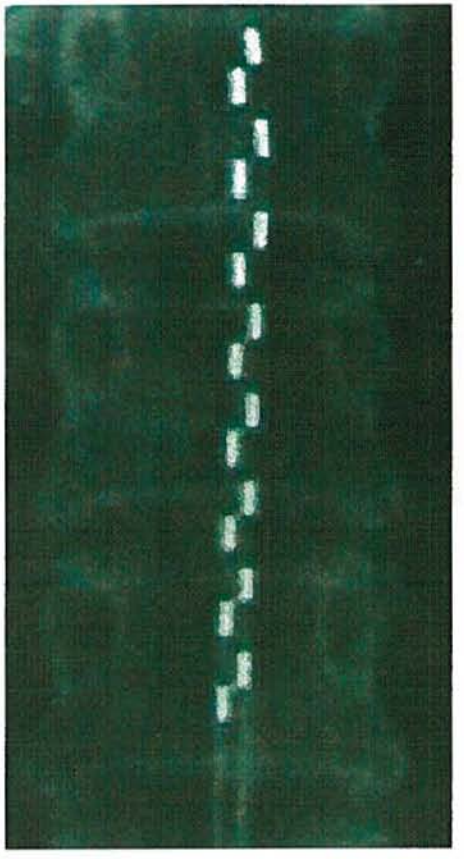
Configuration of SCS Devices

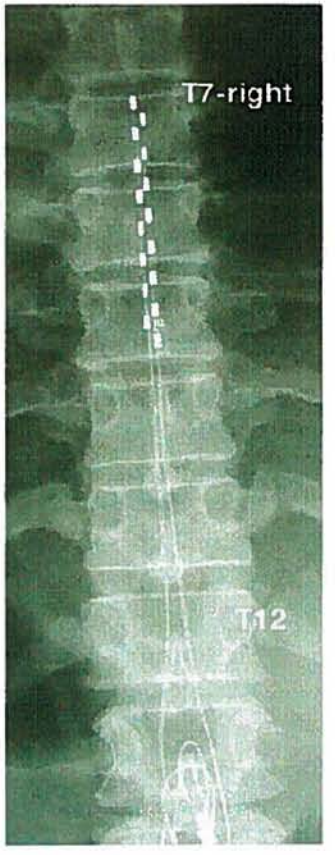
- SCS devices manufactured by ANS and others generally have three main components:
  - Implanted leads
  - Implanted pulse generator (or “transmitter”)
  - Programmer assembly

Evaluation Period

- Evaluation period is FDA-approved for up to 30 days, but typically is 3-5 days
- For evaluation, leads are surgically implanted in the spinal column
- During this period, the generator is worn externally outside the body (body-worn) and connects through the skin to the implanted leads
- Doctors and patients assess the clinical benefit of the device for a particular patient to determine whether full implantation is warranted
- Evaluation minimizes unnecessary surgery and the associated medical costs

Evaluation Procedure





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Evaluation Procedure

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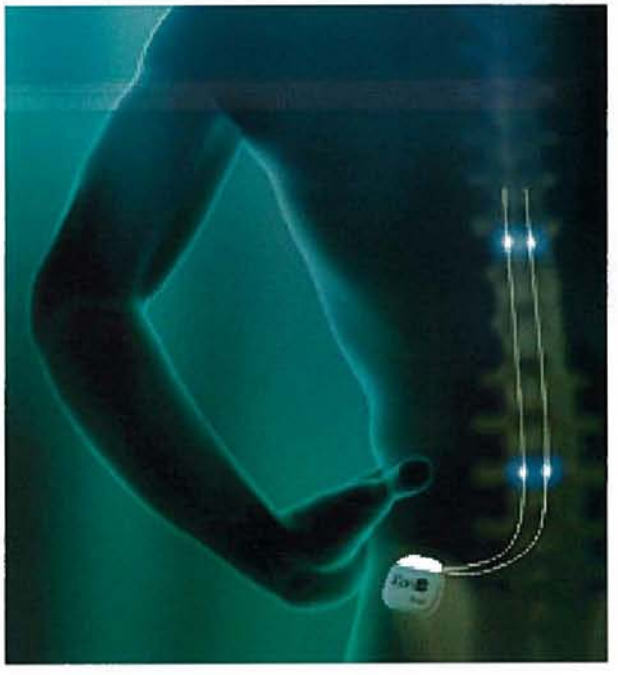
Evaluation vs. Full Implant

Evaluation
(up to 30 days)

Full Implant
(permanent)



ANS
A St. Jude Medical Company

Body-Worn Transmitters – MedRadio

- Body-worn transmitters connected through the skin to a **surgically implanted** medical device should be permitted to operate at 402-405 MHz if:
  - There is a sound diagnostic or therapeutic justification for operating the transmitter as a body-worn device
  - The body-worn transmitter is intended to be replaced by a permanently implanted transmitter after a brief period
  - The body-worn transmitter is "listen before talk" and "frequency agile"
  - The body-worn transmitter operates at an appropriate measured field strength limit
  - The body-worn transmitter otherwise complies with FCC requirements applicable to implanted transmitters
  - Once the transmitter is implanted, the medical device will meet all applicable FCC requirements.

Public Interest

- Permitting operation of temporary body-worn transmitters meeting the foregoing criteria would serve the public interest by:
  - Maximizing patient safety and therapeutic benefits
  - Minimizing healthcare costs
  - Posing little if any risk of harmful interference at 402-405 MHz

Public Interest *(continued)*

- Relegating such transmitters to spectrum outside of 402-405 MHz would harm the public interest by:
  - Depriving doctors of ability to predict efficacy of devices once implanted, due to disparity in frequencies
  - Likely subjecting body-worn transmitters to unacceptable interference or other operational difficulties