



1350 I Street, NW
Suite 540
Washington, DC 20005
P: (202) 354-7171
F: (202) 357-7176

**Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554**

In the Matter of)
)
Modification of Parts 2 and 15 of the Commission's Rules for) ET Docket No. 03-201
unlicensed devices and equipment approval.)
)
)

COMMENTS OF THE MEDICAL DEVICE MANUFACTURING ASSOCIATION

The Medical Device Manufacturing Association (MDMA) respectfully submits its comments in the above-captioned proceeding. These comments respond to the *Memorandum Opinion and Further Notice of Proposed Rule Making* ("the Notice") released by the Commission on June 22, 2007.¹ MDMA supports spectrum etiquette for devices operating under Section 15.247 in the 902-928 MHz band (the "915 MHz band") to promote continued coexistence of devices in the band. MDMA opposes spectrum etiquette for devices operating under Section 15.249 to allow design flexibility in lower power devices.

BACKGROUND AND SUMMARY

The Medical Device Manufacturers Association ("MDMA") is a national trade association that represents over 160 independent manufacturers of medical devices, diagnostic products and healthcare information systems.² Among other objectives, MDMA seeks to ensure that patients have access to the latest advancements in medical technology, many of which are developed by small, research-driven medical device companies. In particular, MDMA member companies manufacture medical devices that make new and innovative uses of the 900 MHz spectrum band under Part 15 of the FCC's rules. Such uses include devices such as:

- Implantable cardiac devices enabled with radio frequency telemetry
- Wireless patient monitoring devices
- Wireless electrocardiogram transmitters

¹ *In the Matter of Modification of Parts 2 and 15 of the Commission's Rules for Unlicensed devices and equipment approval*, ET Docket No 03-201, Memorandum Opinion and Order and Further Notice of Proposed Rulemaking (released June 22, 2007).

² MDMA was created in 1992 by a group of medical device company executives who believed that the innovative and entrepreneurial sector of the industry needed a strong and independent voice in the nation's capital. Our mission is to promote public health and improve patient care through the advocacy of innovative, research-driven medical device technology.

- Artificial hearts

Such devices – all of which operate at very low power – have important benefits. Among other things, they allow patients to spend less time in hospitals and doctors' offices, permit physicians to monitor patients remotely, and enhance the overall quality of life of critically ill patients.

Design considerations for such devices can be very strict. For example, implanted cardiac devices reside for years within a patient's body, so low power consumption directly impacts battery longevity, which is particularly important in the design of the telemetry systems for these devices. Some of these devices are designed to operate in the 915 MHz ISM band to take advantage of the higher power limits compared with other options such Medical Implant Communications System (MICS) in the 400 MHz frequency band. Many of these medical devices operate under Section 15.249.

It is important that the 915 MHz band continue to be broadly available for medical telemetry as an alternative to the lower power MICS band: Patients, physicians, and other clinical users should continue to have effective access to technology that utilizes the 915 MHz band. To this end, MDMA generally supports spectrum etiquette for devices operating in the 915 MHz band under Section 15.247 to manage potential interference, and generally opposes spectrum etiquette for devices operating under Section 15.249 to allow continued flexibility in the design of ultra-low power medical telemetry systems.

DISCUSSION

I. **Devices Operating under Section 15.247 Should be Subject to Spectrum Etiquette Rules to Promote Continued Coexistence of Unlicensed Devices in the Band.**

MDMA generally supports adoption of spectrum etiquette in the 915 MHz band to allow continued coexistence of unlicensed devices in the band. In particular, MDMA supports spectrum etiquette for heavy users of the band, e.g. for high power spread spectrum devices. High power spread spectrum transmissions could have a greater range for potential interference with other Part 15 users, and some transmitters may not have the sensitivity to detect other low power transmitters in range. Spectrum etiquette could mitigate the risk that low power users such as low power medical devices would be interfered with but not detected.

Many patients benefit from the system flexibility and monitoring capability provided by the various medical devices that operate in the 915 MHz band. The 915 MHz band should be managed to allow continued flexible operation of low power medical devices in the band. To this end, spectrum etiquette should be applied to device operating under 15.247 to promote the continued flexible use of the band for managing and monitoring medical devices and the medical condition of patients who benefit from these devices.

II. **Certain Aspects of the Spectrum Etiquette Should Not Apply to Devices Operating under Section 15.249**

MDMA believes that devices operating under 15.249 are less likely to cause interference than devices operating under 15.247. Thus, while MDMA supports spectrum etiquette, MDMA generally opposes application of spectrum etiquette to devices that operate under Section 15.249 to preserve the design flexibility afforded by that Section.³ In particular, MDMA opposes the application of the proposed duty cycle and power restrictions to devices that operate under Section 15.249.⁴ Ultra-low power medical telemetry systems such as those in implantable devices typically have very short range (<10 m). This class of device benefits from the availability of continuous device interrogation during a telemetry session. Even in busy clinical settings, interruptions in the telemetry channel and data flow to meet duty cycle requirements would only serve to reduce longevity of battery-powered devices, due to increased transmission requirements. This could result in providers having to explant and replace a device sooner and more often due to the now shortened device life cycle.

MDMA also opposes a "listen-before-talk" (LBT) etiquette for devices operating under Section 15.249.⁵ Requiring an LBT etiquette for all devices could result in similar delays to telemetry sessions, increased power consumption, and shortened device longevity for implanted devices.

MDMA also opposes an absolute prohibition on synchronization of transmissions from multiple devices in a system.⁶ Future generations of medical telemetry systems operating under 15.249 may carry multiple sessions to allow flexibility and efficiency for patients and clinics.

³ Paragraph 26 of the Notice seeks comments on applicability of spectrum etiquette under Section 15.249.

⁴ See paragraphs 18-24 of the Notice.

⁵ See Notice, paragraph 23.

⁶ See Notice, paragraph 24

MDMA supports permitting automatic changes to the power levels and duty cycles at which devices operate under Section 15.249.⁷

In sum, patients and clinics benefit from the efficiency and design flexibility afforded to medical devices under Section 15.249, and that efficiency and flexibility should not be compromised by application of spectrum etiquette rules to very low power medical devices.⁸

III. Any Transition Should Account for Long Lead Times Associated with Medical Device Design and Manufacture.

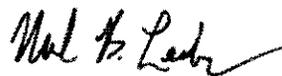
To the extent that any rule changes affect implanted medical devices and related systems, the transition provisions should take into account the long lead times for developing, testing, and seeking regulatory approval for medical devices.⁹ Devices previously certified under Section 15.249 should be indefinitely permitted (i.e. permanently "grandfathered in"). Any changes to Section 15.249 should account for medical devices under development and provide long notice periods to avoid disruption multi-year design, test, and approval processes.

CONCLUSION

For these reasons, MDMA urges the FCC to adopt spectrum etiquette for devices operating under Section 15.247 and urges the FCC to refrain from applying the same spectrum etiquette rules to devices operating under Section 15.249.

Respectfully submitted,

Medical Device Manufacturers Association



By: /s/
Mark B. Leahey
Executive Director
1350 I Street NW
Suite 540
Washington, DC 20005

⁷ See Notice, paragraph 25.

⁸ If spectrum etiquette rules are applied to Part 15 devices, MDMA supports an exception for the very narrow class of battery powered medical devices or implantable medical devices, and systems that communicate with such devices, to avoid compromising the battery life or clinical performance of such devices.

⁹ The re-design process potentially can take years due to inherent product complexities, the need for extensive integrated testing, and the sometimes lengthy FDA approval process. While small and growing businesses are among the leading innovators in the medical technology industry, many such businesses can ill afford the time and financial resources to re-design their products.