Recent Developments in Wireless Technology for Medical Applications

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Wireless communications applications for medicine are a rapidly growing part of the wireless industry. Patient monitoring, embedded devices, access to records, image transmission for diagnosis and analysis, and many other systems are now being proposed, designed or manufactured. This report presents recent regulatory activity, as well some product news in this area of technology.

FCC-FDA Cooperate on Wireless Medical Technologies and Applications

In late July 2010, the Food and Drug Administration (FDA) and Federal Communications Commission held a meeting to establish a cooperative program to enable the development, regulation and approval of wireless medical devices. The agencies have overlapping authority in this area with regard to spectrum usage, electromagnetic compatibility and RF exposure. Following the July 2010 meeting, a joint statement from FDA Commissioner Dr. Margaret Hamburg, and FCC Chairman Julius Genachowski set forth these objectives:

1. Innovation in broadband and wireless-enabled medical devices holds significant promise for enhancing health and reducing the costs of health care for all Americans. Examples include wireless sensors that remotely monitor heart rhythm and portable glucose monitoring systems. All Americans should be afforded the opportunity to benefit from medical technology advances with improved broadband and wireless technology.

2. Developing and integrating wireless and broadband communications technology with medical devices and applications requires agencies to assure that such devices operate in a safe, reliable and secure manner.

3. It is important for the federal government to provide leadership and encourage innovation and investment in new health care technologies that enable patients, doctors, and other health professionals to access the highest quality care.

4. The American public—including industry, providers, patients, and other interested stakeholders—should have clear regulatory pathways, processes, and standards to bring broadband and wireless-enabled medical devices to market. This includes clarity regarding each agency's scope of authority with respect to these devices, predictability regarding regulatory pathways, and streamlining the application process, as appropriate, to facilitate innovation while protecting patients.

5. The FDA and the FCC agree to build upon this initiative launched today to proactively serve the national interest in finding innovative solutions to America's health care challenges.

CDRH Innovation Inititative

In February 2011, the Center for Devices and Radiological Health at the U.S. Food and Drug Administration announced a Medical Device Innovation Initiative. As part of this initiative, CDRH outlined additional actions the Center might take to encourage innovation, streamline regulatory and scientific device evaluation, and expedite the delivery of novel, important, safe and effective innovative medical devices to patients.

The Innovation Initiative proposes actions CDRH could take to help accelerate and reduce the cost of development and regulatory evaluation of innovative medical devices safely and based on sound science. Although the Innovation Initiative does not list specific technologies, many potential applications would use wireless communications, or use inductive wireless power transfer for recharging batteries in implanted devices.

Jeffrey Shuren, M.D., J.D., Director of the CDRH, commented, "Perhaps most exciting is our proposal to establish a priority review program for eligible, new medical devices that demonstrate the potential to revolutionize disease treatment, diagnosis, or health care delivery and that target unmet medical needs. Under the Innovation Pathway, the FDA's medical device center would commit time and resources much earlier in product development so that innovators of new, safe and effective technologies can reach the U.S. market more quickly and efficiently."

Aingeal Wireless Monitor Gets FDA Clearance

Intelesens, a Belfast wireless health monitoring company, has received formal confirmation that their wearable wireless hospital monitor, Aingeal, has been awarded class 2 regulatory approval by the FDA authorities in the USA. Following the completion of successful clinical

trials in Massachusetts General Hospital in Boston last year, FDA clearance now enables the company to deploy Aingeal into US hospitals and healthcare organisations. Aingeal received its European CE class 2 approval last year.

The Aingeal device enables patients to be monitored, continuously and wirelessly, from the moment they arrive in a hospital until the time they are discharged. Where currently monitored patients are restricted to their hospital beds, the Aingeal body worn monitor allows free movement. The Aingeal device is unique in that it measures the patient's ECG, heart rate, respiration rate, temperature and motion and sends that information wirelessly so that it is immediately and easily accessible by nursing and other medical staff. Clinicians can access the patient data through any web browser freeing them from paper charts and records and reducing the costs of taking routine observations.

Wireless LAN Module For Medical Applications

connectBlue's OWS451 Wireless LAN Serial Port Module is a replacement for a serial cable in industrial and medical applications. Since the Serial Port Module has the TCP/IP stack and software embedded, it also offers a seamless connection between a device and the existing 2.4 GHz or 5 GHz Wireless LAN network. The OWS451 has support for dual-band operation that makes it easier to utilize interference-free channels and to connect to networks that operate in either the 2.4 or the 5 GHz radio bands. Dual-band operation has become a user requirement in factory and hospital environments due to the increase of 2.4 GHz devices. Hospitals as well as process and factory industries have allocated channels in the 5 GHz band exclusively for industrial and medical devices.

The module is compatible with the existing connectBlue Wireless LAN, Bluetooth and IEEE 802.15.4/ZigBee product through connectBlue's standard electrical, mechanical, software and antenna interfaces. The Serial Port Module also offers compatibility of Enhanced Enterprise Security which makes it possible to connect to existing Wireless LAN networks that utilize these security systems.

Multilingual Medical Communication Device

Sierra Wireless and GeaCom, Inc. have announced that GeaCom has selected a Sierra Wireless AirPrime™ embedded wireless module to provide the 3G wireless connection for GeaCom's Phrazer® multilingual medical communication system. Phrazer is a handheld touchscreen device that helps patients and caregivers overcome differences in language, culture, or literacy to exchange critical medical information. With the integrated wireless module, the Phrazer device can instantly access and update patient information within an electronic health records (EHR) system from any location, even at an accident site or while in transit to hospital, using a cellular data network.