



December 13, 2007

Commission's Secretary  
Office of the Secretary  
Federal Communications Commission  
445 12th Street, SW  
Washington, DC 20002

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) has concerns regarding the present petition submitted by Veroscan to increase the radio frequency (RF) output power of their RFID sponge detection device system up to 25 W conducted power because the increased emissions from the Veroscan device could cause electromagnetic interference (EMI) to nearby active medical devices that might compromise patient safety. Interference with critical monitoring equipment or other potentially susceptible medical devices and systems could present higher risks for patient safety, degrade device effectiveness, and/or potentially result in serious patient consequences.

Our concerns are based on the typical radiated immunity of critical medical devices used in the patient environment and recent FDA laboratory testing that showed the emissions from conventional RFID systems with significantly lower RF output than the Veroscan proposal may affect the function of certain implantable cardiac pacemakers and defibrillators [1]. Our laboratory testing was performed in conjunction with the Association for Advancement of Medical Instrumentation (AAMI) Cardiac Rhythm Management Devices Committee's Electromagnetic Compatibility Task Force that included several cardiac medical device manufacturers and RFID manufacturers. Given the results we have seen, the additional RF power output proposed for the Veroscan system may present an increased potential for adverse effects on critical medical devices such as life-supporting and monitoring equipment that are likely to be used in proximity to the Veroscan device.

The increased emission levels proposed in the Veroscan petition and resulting exposure would likely exceed the design and immunity testing for most active medical devices that could be in proximity. Further, according to the recommendations in the IEC 60601-1-2 standard for medical electrical equipment, which is applicable to non-implantable medical devices used in the patient vicinity, RF sources with 25 W output at the carrier frequency used by the Veroscan device should be separated from active medical devices and systems by at least 11 meters (36 ft). This would suggest the Veroscan device could not be used in the vicinity of other active medical devices as the sponsor of Veroscan describes in their petition, even for limited time periods. The information provided by Veroscan in its petition request does not adequately address our concerns about the potential increased risks posed by the increase in RF output power.

We note that Veroscan's request for waiver of section 15.247(b) states that it "recently secured an exemption from approval from the Food and Drug Administration" and attaches FDA's response dated August 6, 2007, to a request from Veroscan submitted to FDA under section 513(g) of the Federal Food, Drug, and Cosmetic Act. In our letter, however, we explain that our response is based solely on the information provided to us, is not a classification decision, and does not constitute clearance or approval for commercial distribution. The letter also explained that there are limitations on the exemption for the device type identified.

Sincerely,



William A. Herman  
Acting Director  
Office of Science and Engineering Laboratories  
Center for Devices and Radiological Health  
Food and Drug Administration

1. Seth J. Seidman, Paul S. Ruggera, Randall G. Brockman, Brian Lewis, Mitchell J. Shein, Electromagnetic compatibility of pacemakers and implantable cardiac defibrillators exposed to RFID readers, *International Journal of Radio Frequency Identification Technology and Applications* 2007 - Vol. 1, No.3 pp. 237 - 246