# 1 Executive Summary

This report references two detailed reports:

NWEMC Testing Report CAME0008, Cameron Health SQRX Pulse Generator (Referred to below as NWEMC – SQRX) - subject of this current application for equipment authorization.

NWEMC Testing Report CAME0007 Rev.2, Cameron Health Q-TECH Programmer (Referred to below as NWEMC – Q-TECH) - subject to a separate application for equipment authorization.

This report documents the testing and test results showing compliance with applicable sections of the FCC Regulations relating to the operational aspects of the Cameron Health SQRX Pulse Generator. The SQRX Pulse Generator is part of the Cameron Health S-ICD® System, which also includes the Q-TECH Programmer. To the extent necessary, this report will include discussion or analysis of relevant features of the Q-TECH Programmer.

# 2 Applicable Regulations

The SQRX Pulse Generator is intended for use as an implantable medical device having telemetry capabilities intended to use the Medical Implant Communications Service band (MICS). This document covers:

| | | |
|---|---|---|
| §95.628 | MICS Transmitters | Subparts (a)-(f) |
| §95.631 | Emission Types | Subpart (h) MICS Stations |
| §95.633 | Emission Bandwidth | Subpart (e) For transmitters in the MICS |
| §95.635 | Unwanted Emissions | Subpart (d) For transmitters designed to operate in the MICS |
| §95.639 | Maximum Transmitter Power | Subpart (f) |
| §95.645 | Control Accessibility | |
| §95.649 | Power Capability Controls | |

This report does not cover the requirement stated in §95.603(f) for radiofrequency radiation exposure requirements, as the indicated requirements in §§1.1307 and 2.1093 of that section are covered in a separate report. Several subsections that are identified above are applicable to only one of the SQRX or Q-TECH. Sections that do not apply for this report are indicated in the table below. For "system" requirements, reference is made to testing reports for both the SQRX and Q-TECH.

An additional applicable regulation at §95.605 and §95.639(g) states that MICS transmitters must be tested for emissions and EIRP limit compliance while enclosed in a medium that simulates human body tissue in accordance with FCC-specified procedures. Where these regulations are applicable, NWEMC – SQRX states the use of the human body tissue fixture and medium.

# 3 Section-by-Section Analysis

| Rule | Subject Matter | Req. Met? | Applicable Report(s) | Comments |
|---|---|---|---|---|
| §95.628(a) | Monitoring System Requirements | n/a | n/a | Applies to the external programmer. |
| §95.628(b) | MICS Communications initiated by implant | Yes | n/a | The SQRX does not have the ability to initiate a communication session by itself. |
| §95.628(c) | Reference to out of band attenuation per §95.635 | Yes | n/a | See §95.635 below. |
| §95.628(d) | Authorized emission bandwidth less than 300 kHz – single device.<br>Authorized emission bandwidth less than 300 kHz – session requirement. | Yes | NWEMC – SQRX &<br>NWEMC - Q-TECH | NWEMC - SQRX shows BW of 107 kHz (pp 36-39) centered at 403.512-403.514 MHz (pp 32-35).<br>NWEMC - Q-TECH shows BW of 100.8 kHz (pp 36-39) centered at 403.514-403.516 kHz (pp 40-45). Combined numbers demonstrate session BW less than 300 kHz. |
| §95.628(e)(1) | Frequency stability for medical implant transmitter. | Yes | NWEMC – SQRX | NWEMC – SQRX shows frequency stability of better than 100 ppm over temperature range (pp 32-35). |
| §95.628(e)(2) | Frequency stability for programmer. | n/a | n/a | Applies to the external programmer. |

| Rule | Subject Matter | Req. Met? | Applicable Report(s) | Comments |
|---|---|---|---|---|
| §95.628(f) | "The provisions of this section shall not be used to extend the range of spectrum occupied over space or time for the purpose of denying fair access to spectrum for other MICS devices." | Yes | n/a | The Applicant has no such intent. The SQRX EIRP for the fundamental emission is well below allowed maximum (30 dB less than allowed max, as measured at the fundamental transmission in NWEMC-SQRX, pp 27-31), the SQRX cannot initiate a session by itself, and the SQRX is configured to terminate transmissions if a session is ended by the programmer and if a session terminates as indicated by failure to identify a received signal from the programmer. |
| §95.631(h) | "A MICS station may transmit any emission type appropriate for communications in this service. Voice communications, however, are prohibited." | Yes | n/a | The SQRX is not capable of capturing voice and is not programmed to transmit voice communications. |
| §95.633(e)(1) & (e)(3) | Emission Bandwidth less than 300 kHz, measured to 20 dB down points using approximately 1 % RBW. | Yes | NWEMC – SQRX | NWEMC – SQRX shows a bandwidth of 107 kHz (pp 36-39), measured by NWEMC using applicable guidelines. |
| §95.633(e)(2) | Less than 300 kHz BW may be used, provided that unwanted emissions are attenuated per §95.635 and power radiated in any 300 kHz BW does not exceed 25 μW EIRP. | Yes | NWEMC – SQRX | Three items indicated: NWEMC – SQRX shows bandwidth of 107 kHz (pp 36-39), attenuation guidelines met (pp 10-19), and fundamental meets the maximum EIRP limit (pp 27-31). |
| §95.635(d)(1) | Unwanted Emissions out of MICS Band. | Yes | NWEMC – SQRX | NWEMC – SQRX shows tests performed as "Receiver Spurious Emissions" and "Field Strength of Radiated Emissions," and tests passed (pp 10-14 and 20-26). |
| §95.635(d)(2-3) | Test methods for (d)(1) and (d)(4-5). | Yes | NWEMC – SQRX | NWEMC – SQRX shows the emissions tests were performed as set forth in the regulations (pp 10-31). |

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| Rule | Subject Matter | Req. Met? | Applicable Report(s) | Comments |
|---|---|---|---|---|
| §95.635(d)(4-5) | Unwanted emissions within and adjacent to MICS Band. | Yes | NWEMC – SQRX | NWEMC – SQRX shows this test performed as "Emission Mask," and indicates the test is passed (pp 15-19). |
| §95.639(f) | Maximum Transmitter Power less than 25 μW, measured using human body test fixture. | Yes | NWEMC – SQRX | NWEMC – SQRX shows this test performed as "Field Strength of Fundamental" and indicates that the PG passes with more than 30 dB of margin to the specified level (pp 27-31). |
| §95.645 | "No control, switch or other type of adjustment which, when manipulated, can result in a violation of the rules shall be accessible from the transmitter operating panel or from exterior of the transmitter enclosure." | Yes | n/a | No such controls are accessible to the user. |
| §95.649 | "No … MICS … unit shall incorporate provisions for increasing it transmitter power to any level in excess of the limits specified in §95.639." | Yes | n/a | No such controls are accessible to the user. |