FARO Laser Line Probe Safety Statement

Pursuant to the regulations for the administration and enforcement of the Radiation Control for Health and Safety Act of 1968 (Title 21, Code of Federal Regulations, Subchapter J), an annual report titled ANNUAL REPORT ON LASER PRODUCTS (NON-MEDICAL): FOR THE FARO LASER LINE PROBE VERSION 3 and 4 FARO LASER SCANARM, was submitted on August 29, 2013 and assigned accession number 1331138-000; and FOR VERSION 5 FARO LASER SCANARM, was submitted on July 11, 2013 and assigned accession number 1320392-000, pursuant to Section 1002.12 of the Regulations. The product report identifies the product as a CDRH Class 2M product that includes a purchased laser module whose output does not exceed CDRH Class 2M and IEC Class 2M requirements for safety. The report finds the product is compliant with the requirements of 21 CFR PART 1040 PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS, Sec. 1040.10 Laser Products.

Based on a review of the Product Report submitted to the U.S. Center for Devices and Radiological Health (CDRH), the FARO Laser Line Probe satisfies the requirements in the amended IEC 60825-1 Laser Safety Standard and EN 60825-1. LEDs included in the product are of the surface-emitting type. The International Commission on Non-Ionizing Radiation Protection (ICNIRP) has found that such devices are safe and provide no hazard to the eye.