Medical & Radiation Emitting Device Recalls

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Medical & Radiation Emitting Device Recalls

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Class 2 Recall
Candela Laser

Date Classified
November 18, 2013

Recall Number
Z-0348-2014

Product
Candela Laser GentleLase Pro, Powered Laser Surgical Instrument for dermatological use - Model number: 9914-00-9015, and Candela Laser GentleLase Pro LE, Model number: 9914-00-9040

Code Information
GL Pro Model 9914-00-9015: SN 9914-9015-0005 through 9914-9015-1258 GL Pro LE Model 9914-00-9040: SN 9914-9040-0716 through 9914-9040-1214

Recalling Firm/
Manufacturer
Candela Corporation
530 Boston Post Rd
Wayland, Massachusetts 01778-1833

Manufacturer Reason
Unintended single pulse maybe emitted to handpiece prior to pressing of trigger or footswitch and cause injury.

Action
Candela notified Distributors on 11/8/13 through e-mail, Certified return receipt request, or FedEx package containing distributor letter, customer letter for translation and customer lists. A software update to Version 2.0 will be issued to the user by a field service representative.

Quantity in Commerce
1268 units

Distribution
Nationwide Foreign: Azerbaijan, Bulgaria, Chile, Czech Republic, Greece, Israel, Kuwait, Qatar, Saudi Arabia, Serbia, Turkey, and the United Arab Emirates and to Subsidiaries in Australia, France, Germany, Italy, Japan, Portugal, Spain, and the United Kingdom

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12/10/2013