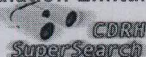


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**Medical & Radiation Emitting Device Recalls**

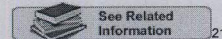


510(k)<sup>7</sup> | Registration & Listing<sup>8</sup> | Adverse Events<sup>9</sup> | Recalls<sup>10</sup> | PMA<sup>11</sup> | Classification<sup>12</sup> | Standards<sup>13</sup> | Inspections<sup>14</sup> | CFR Title 21<sup>15</sup> | Radiation-Emitting Products<sup>16</sup> | X-Ray Assembler<sup>17</sup> | Medsun Reports<sup>18</sup> | CLIA<sup>19</sup> | TPLC<sup>20</sup>

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**Class 2 Recall  
Candela Laser**



<b>Date Classified</b>	November 18, 2013
<b>Recall Number</b>	Z-0348-2014
<b>Product</b>	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
<b>Code Information</b>	GL Pro Model 9914-00-9015:: SN 9914-9015-0005 through 9914-9015-1259 GL Pro LE Model 9914-00-9040: SN 9914-9040-0716 through 9914-9040-1214
<b>Recalling Firm/ Manufacturer</b>	Candela Corporation 530 Boston Post Rd Wayland, Massachusetts 01778-1833
<b>Manufacturer Reason for Recall</b>	Unintended single pulse maybe emitted to handpiece prior to pressing of trigger or footswitch and cause injury.
<b>Action</b>	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.
<b>Quantity in Commerce</b>	1258 units
<b>Distribution</b>	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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