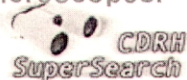




FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>  
**Class 2 Device Recall Cell Observer SD, Laser TIRF, and DirectFRAP Laser Scanning Microscopes.**

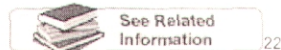


6 510(k)<sup>7</sup>|DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup>|PMA<sup>12</sup>|HDE<sup>13</sup>|Classification<sup>14</sup>|Standards<sup>15</sup>  
 CFR Title 21<sup>16</sup>|Radiation-Emitting Products<sup>17</sup>|X-Ray Assembler<sup>18</sup>|Medsun Reports<sup>19</sup>|CLIA<sup>20</sup>|TPLC<sup>21</sup>

[New Search](#)

[Back to Search Results](#)

**Class 2 Device Recall Cell Observer SD, Laser TIRF, and DirectFRAP Laser Scanning Microscopes.**



<b>Date Initiated by Firm</b>	May 08, 2018
<b>Create Date</b>	June 09, 2018
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-2058-2018
<b>Recall Event ID</b>	80115 <sup>23</sup>
<b>Product Classification</b>	<a href="#">Spectroscopy instrument<sup>24</sup></a> - <a href="#">Product Code REM<sup>25</sup></a>
<b>Product</b>	Carl Zeiss Microscopy for Laser Scanning Microscopes (Cell Observer SD, Laser TIRF and DirectFRAP  Laser scanning microscopes are used in cell biology research.
<b>Code Information</b>	Model No. Cell Observer SD, Laser TIRF, and DirectFRAP Laser Scanning Microscopes
<b>Recalling Firm/Manufacturer</b>	Zeiss, Carl Inc 1 Zeiss Dr Thornwood NY 10594-1939
<b>For Additional Information Contact</b>	914-747-1800
<b>Manufacturer Reason for Recall</b>	In certain eyepiece configurations the laser shutter may not close completely, permitting reflected beams that may be greater than the Class I limit.
<b>FDA Determined Cause<sup>2</sup></b>	Radiation Control for Health and Safety Act
<b>Action</b>	1. Your firm will send an initial email to all known users advising them of the issue, the risk involved and associated mitigations until the units can be evaluated by Carl Zeiss service representatives. 2. Your firm will send a second written communication to each first line purchaser and to each known user site with the notice of action and warning to discontinue use of the component until it has been verified as defective or properly functioning, and 3. Your firm will dispatch factory trained service representatives to perform verification tests and to replace defective units as necessary, free of charge. CDRH approves the CAP subject to the following conditions: For further questions, please call (914) 747-1800. 1. Notification of all dealers and purchasers is to be made within 15 working days of receipt of this letter in the manner specified in 21 CFR 1003.21 and 1003.22. This office and the Food and Drug Administration (FDA) district office coordinator noted below are to be included in the notification. 2. Corrective actions will be provided at no cost to the purchasers and completed by March 1, 2019.
<b>Quantity in Commerce</b>	107 units to US
<b>Distribution</b>	USA (nationwide)
<b>Total Product Life Cycle</b>	TPLC Device Report <sup>26</sup>