FDA

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

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See Related Information [22]

Date Initiated by Firm	May 08, 2018
Create Date	June 09, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-2058-2018
Recall Event ID	80115[23]
Product Classification	Spectroscopy instrument[24] - **Product Code** REM[25]
Product	Carl Zeiss Microscopy for Laser Scanning Microscopes (Cell Observer SD, Laser TIRF and DirectFRAP Laser scanning microscopes are used in cell biology research.
Code Information	Model No. Cell Observer SD, Laser TIRF, and DirectFRAP Laser Scanning Microscopes
Recalling Firm/ Manufacturer	Zeiss, Carl Inc 1 Zeiss Dr Thornwood NY 10594-1939
For Additional Information Contact	914-747-1800
Manufacturer Reason for Recall	In certain eyepiece configurations the laser shutter may not close completely, permitting reflected beams that may be greater than the Class I limit.
FDA Determined Cause [2]	Radiation Control for Health and Safety Act
Action	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.
Quantity in Commerce	107 units to US
Distribution	USA (nationwide)
Total Product Life Cycle	TPLC Device Report[26]