Class 2 Device Recall Lumenis M22 System

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See Related Information[22]

Recall Date	May 13, 2016
Recall Status[1]	Open
Recall Number	Z-1669-2016
Recall Event ID	73765[23]
510(K)Number	K142860[24]
Product Classification	Powered laser surgical instrument[25] - **Product Code** GEX[26]
Product	Lumenis M22 System Model Number: GA-0005400 (M22 IPL + YAG Module) with Acne Filter (KT-1014971).
Code Information	Lumenis M22 System Model Number: GA-0005400 (M22 IPL + YAG Module) All Acne Filters manufactured and Distributed Between: August 04 2015 and November 06 2015
Recalling Firm/ Manufacturer	Lumenis Ltd 13 Hayetzira St.,Yokneam Ind. Park Yokneam Israel
Manufacturer Reason for Recall	Lumenis Ltd Announces a Field Action of the M22 IPL Acne Filters for the Lumenis M22 IPL Hand Piece due to the Risk of Superficial Burns When Using the Device.
FDA Determined Cause [2]	Device Design
Action	Customers were notified on November 17, 2015 by Customer Notification Letter and customers were asked to return the device.
Quantity in Commerce	33 filters
Distribution	Distributed in the states of GA, CA, CO, CT, KY, LA, MA, MN, NJ, NY, RI, and SC, and the countries of Italy, Germany, France, and China.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = GEX and Original Applicant = Lumenis Ltd.[29]

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