Class 2 Recall
Apollo Therapy Laser

See Related Information[23]

Date Posted	March 06, 2015
Recall Status[1]	Open
Recall Number	Z-1250-2015
Recall Event ID	70473[24]
Premarket Notification 510(K) Number	K060134[25]
Product Classification	Lamp, Infrared, Therapeutic Heating[26] - **Product Code** ILY[27]
Product	Apollo (cold) Laser Desktop Control Units, Model AP2-DT. The Apollo IR Heat Lamp System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and / or promoting relaxation of muscle.
Code Information	DT-1102, 1105, 1106, 1109, 1110, 1112,1114, 1115, 1116, 1118,1119, 1120, 1121, 1121, 1122, 1123, 1124, 1125, 1126, 1127, 1128, 1129, 1130, 1131, 1132, 1134, 1135, 1136, 1137, 1138, 1139, 1302, 1303, 1304, 1309.
Recalling Firm/ Manufacturer	Pivotal Health Solutions 724 Oakwood Road Watertown, South Dakota 57201-4133
For Additional Information Contact	Robin Hartley 800-743-7738
Manufacturer Reason for Recall	Control units were equipped with an internal mounting kit that does not meet medical safety standards, and are conductive, increasing the risk of electric shock to the user and patient. These units were manufactured prior to Pivotal Health Solutions acquisition of the Apollo product line.
FDA Determined Cause [2]	DESIGN: Device Design
Action	The firm, Pivotal Health Solutions, sent a letter dated December 17, 2014 on 12/17/2014 and an amended Pivotal "Urgent Medical Device Recall" letter dated February 9, 2015 to its consignees/customers. The letters described the product, problem and actions to be taken. The consignees/customers were instructed to stop using the unit and contact Pivotal Health Solution's at 1-800-743-7738 to arrange for return and repair asap; immediately examine your device inventory and quarantine any product subject to recall; if you have further distributed the product, identify your customers and notify them at once of this product recall, and complete and return the enclosed RETURN AUTHORIZATION FORM with the units to Pivotal Service Center, 1654 Mardon Drive, Dayton, OH 45432 and the DECLARATION OF CONTAMINATION STATUS form via Fax to: 605-882-8398. If you have any questions, contact Pivotal Health Solutions Service Repair Coordinator at 800-743-7738 or email Robin@PivotalHealthSolusitons.com.
Quantity in Commerce	35
Distribution	US Distribution to states of: AZ, AR, CA, GA, IL, IN, IA, KS, MI, MN, MO, NY, OH, OR, PA, UT and WA.