Class 2 Device Recall Berchtold Chromophare

See Related Information[22]

Date Initiated by Firm	April 21, 2017
Create Date	June 05, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2248-2017
Recall Event ID	77261[23]
Product Classification	Device, medical examination, ac powered[24] - **Product Code** KZF[25]
Product	Berchtold Chromophare F300 Exam Light CHROMOPHARE examination lights are medical lights used for local illumination of the patients' body so that illnesses, injuries and disabilities can be diagnosed and treated
Code Information	Serial Numbers: 7735170-X68377, 7735170-X68397,, 7735170-X14846, 7735170-X15688, 7735170-X14492, 7735170-X14495,, 7735170-X14497, 7735170-X14501, 7735170-X14502, 7735170-X14504, 7735170-X14506, 7735170-X14507, 7735170-X14508, 7735170-X14510, 7735170-X68383, 7735170-X68384, 7735170-X68385, 7735170-X68386, 7735170-X68393, 7735170-X68394, 7735170-X68395, 7735170-X68396, 7735170-X68392, 7735170-X68400, 7735170-X68401, 7735170-X15607, 7735170-X15608, 7735170-X15609, 7735170-X15610, 7735170-X15611, 7735170-X15612, 7735170-X15613, 7735170-X15614, 7735170-X15615
Recalling Firm/ Manufacturer	Stryker Communications 1410 Lakeside Pkwy Ste 100 Flower Mound TX 75028-4026
For Additional Information Contact	Julie Baker 972-834-8656
Manufacturer Reason for Recall	The exam light may have a tolerance issue with the adapter assembly, which could potentially not allow the snap ring to be seated correctly. If this is the case, there could be insufficient mount force that may cause the equipment to fall, resulting in serious injury.
FDA Determined Cause [2]	Component design/selection
Action	Stryker Communications sent an Urgent Medical Device Recall letter to all affected customers. A Stryker Representative will contact their facility to schedule a service visit. to replace the adapter assembly to resolve the tolerance issue affected units. Customers with questions were instructed to Stryker Technical Support at 800-243-5135 or comm.techservice@stryker.com. For questions regarding this recall call 972-834-8656.
Quantity in Commerce	57 units
Distribution	Worldwide Distribution - US and Canada
Total Product Life Cycle	TPLC Device Report[26]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA