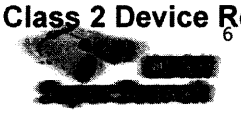
FDA

Class 2 Device Recall Digital Video Capture Modules



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Class 2 Device Recall Digital Video Capture Modules

[22]

Date Initiated by Firm	April 13, 2017
Create Date	July 18, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2742-2017
Recall Event ID	77137[23]
Product Classification	Transformer, endoscope[24] - **Product Code** GCW[25]
Product	7245C, 7245C/E, 7245D Computer Digital Video System Product Usage: The 7245C, 7245C/E and 7245D are used to electronically record, display, transfer, and store digital video data of behavior related to swallowing in the pharyngeal area for medical and pedagogical applications.
Code Information	24966-06, 25281-01, 26060-10, 26874-03, 26874-06, 28669-04, 28671-02, 28671-04, 28675-04, 30150-02, 30150-03, 30604-09, 31525-03, 31525-09, 31526-19, 32945-04, 36453-10, 36453-13, 38476-04, 38476-07, 38748-101, 38976-04, 39444-02, 39471-09, 39508-151, 41735-05, 41735-08, 41735-11, 45810-14, 47969-04, 80397-09, 80400-01, 80850-02, 25631-07, 27406.05, 28677-10, 30737-12, 34599-04, 37836-05, 4124-07, 45735-03, 45810-08, 80910-02
Recalling Firm/ Manufacturer	Pentax of America Inc 3 Paragon Dr Montvale NJ 07645-1782
For Additional Information Contact	800-431-5880
Manufacturer Reason for Recall	Pentax Medical did not always provide transformers with 9175 isolation transformers are used with 7245C, 7245C/E, 7245D, 9200Cs, 9200Ds, 9310HDs, and 9400s computer systems.
FDA Determined Cause [2]	Device Design
Action	Pentax notified their customers on 4/13/2017 via USPS.
Quantity in Commerce	241 units in total
Distribution	Worldwide Distribution - US Nationwide
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 identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated.