Class 2 Device Recall Digital Video Capture Modules

Date Initiated by Firm
April 13, 2017

Create Date
July 18, 2017

Recall Status
Open, Classified

Recall Number
Z-2742-2017

Recall Event ID
7713723

Product Classification
Transformer, endoscope - Product Code GCW25

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, 25060-10, 26874-03, 26874-04, 26874-05, 26874-08, 26875-01, 26875-02, 26875-03, 26875-04, 26875-05, 30150-03, 30150-06, 30150-09, 31525-03, 31525-05, 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, 45910-08, 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
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 Report26

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.