FDA

Class 2 Device Recall C2 CryoBalloon Ablation System

See Related Information[22]

Date Initiated by Firm	December 03, 2018
Create Date	March 01, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-0970-2019
Recall Event ID	81695[23]
510(K)Number	K163684[24]
Product Classification	Unit, cryosurgical, accessories[25] - **Product Code** GEH[26]
Product	C2 CryoBalloon Controller, REF: FG-1017, with Controller Software v1.18.258 The C2 CryoBalloon Ablation System is intended to be used as a cryosurgical tool in the field of general surgery, specifically for endoscopic application and the ablation of dysplastic Barrett s Esophagus.
Code Information	All lot numbers
Recalling Firm/ Manufacturer	PENTAX of America Inc 303 Convention Way Ste 1 Redwood City CA 94063-1465
For Additional Information Contact	650-521-5304
Manufacturer Reason for Recall	The Controller does not detect overpressure in the balloon during the application of non-dosing puffs of Nitrous Oxide, which can contribute to balloon over pressurization, if the intended vent lumen of the catheter is significantly occluded to prevent relieving balloon pressure due to a kinked catheter condition.If a patient is exposed to higher than physiologic pressures, adverse events such as perforation or mucosal laceration may occur.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	On 10/18/18, the firm, Pentax Medical, started contacting US Affected Customers by telephone to inform them of the pending action and to advise they discontinue use and quarantine affected devices. On 12/03/18, "URGENT MEDICAL DEVICE REMOVAL" letters dated 11/16/18 were mailed via USPS Certified Mail to its customers. Customer response forms and Customer Return Material Shipment Labels were mailed with the removal notices. Customers were informed that affected products should not be used and should be returned to the firm. In addition, customers were asked to ensure that all potential users in their facilities are made aware of the removal notice and the recommended actions. Customers