FDA 510(k) Premarket Notification

CLEARED

K190194 C2 CryoBalloon Catheter (Pear), C2 CryoBalloon (Standard), C2 CryoBalloon Controller, C2 CryoBalloon Foot Pedal, C2 CryoBalloon Cartridge

May 31, 2019
116 days to decision

K190194 · Product code: **GEH** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k190194/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Feb 4, 2019
Decision date	May 31, 2019
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pentax Medical, A Division of Pentax of America, Inc.**
Location	Redwood, Ca, CA, US
Contact	Gurvinder Singh Nanda
510(k) history	2 submissions · 2 cleared · 2019-2019