

K190194 C2 CryoBalloon Catheter (Pear), C2 CryoBalloon (Standard), C2 CryoBalloon Controller, C2 CryoBalloon Foot Pedal, C2 CryoBalloon CartridgeMay 31, 2019
116 days to decisionK190194 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190194/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026