

K203024 C2 CryoBalloon Catheter (Pear), C2 CryoBalloon Catheter (Standard), C2 CryoBalloon Controller, C2 CryoBalloon Foot Pedal, C2 CryoBalloon CartridgeNov 24, 2020
53 days to decisionK203024 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k203024/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Oct 2, 2020
Decision date	Nov 24, 2020
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pentax of America, Inc.
Location	West Cadwell, NJ, US
Contact	Gurvinder Singh Nanda
510(k) history	44 submissions · 44 cleared · 2012-2025

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