

K240457 C2 CryoBalloon Ablation System (C2 CryoBalloon Ablation System)Jul 24, 2024
159 days to decisionK240457 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k240457/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Feb 16, 2024
Decision date	Jul 24, 2024
Days to decision	159 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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