

K212814 C2 CryoBalloon Ablation SystemNov 29, 2021
87 days to decisionK212814 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Sep 3, 2021
Decision date	Nov 29, 2021
Days to decision	87 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	William Goeller
510(k) history	44 submissions · 44 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212814/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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