FDA 510(k) Premarket Notification

K212814 C2 CryoBalloon Ablation System

CLEARED

Nov 29, 2021
87 days to decision

K212814 · Product code: **GEH** · General & Plastic Surgery
Source: 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