

K152329 Coldplay CryoballoonApr 13, 2016
239 days to decisionK152329 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k152329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Aug 18, 2015
Decision date	Apr 13, 2016
Days to decision	239 days
Third-party review	No
Summary / Statement	Summary
Other names	Focal Ablation System, Full Ablation System; Swipe Ablation System

APPLICANT

Company	C2 Therapeutics, Inc.
Location	Redwood, Ca, CA, US
Contact	Theresa Brandner-Allen
510(k) history	7 submissions · 7 cleared · 2015-2018

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