FDA 510(k) Premarket Notification

K193619 Cry-Ac®, Cry-Ac-3®, Cry-Baby

CLEARED

Mar 25, 2020
90 days to decision

K193619 · Product code: **GEH** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k193619/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Dec 26, 2019
Decision date	Mar 25, 2020
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Brymill Cryogenic Systems**
Location	Ellington, CT, US
Contact	Paul Sideleau
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**G&L Scientific, Inc.**
Contact	Roshana Ahmed

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov