

**K193619 Cry-Ac®, Cry-Ac-3®, Cry-Baby**Mar 25, 2020  
90 days to decisionK193619 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193619/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>G&amp;L Scientific, Inc.</b>
Contact	Roshana Ahmed

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193619/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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