

K190407 CryoLabApr 22, 2019
60 days to decisionK190407 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Feb 21, 2019
Decision date	Apr 22, 2019
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cryoconcepts LP
Location	Bethlehem, PA, US
Contact	Sam Niedbala
510(k) history	8 submissions · 8 cleared · 2017-2025

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