

K201366 ForwardsJan 21, 2021
244 days to decisionK201366 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	May 22, 2020
Decision date	Jan 21, 2021
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pronova Laboratories BV
Location	Muiden, NL
Contact	Diede Klever
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Stuart R. Goldman

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

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