

K203481 CryoVIVEMay 13, 2021
167 days to decisionK203481 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k203481/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Nov 27, 2020
Decision date	May 13, 2021
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Recensmedical, Inc.
Location	Hwaseong-Si, KR
Contact	Yeonui Lee
510(k) history	7 submissions · 6 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Dave Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203481/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026