FDA 510(k) Premarket Notification

K203481 CryoVIVE

CLEARED

May 13, 2021
167 days to decision

K203481 · Product code: **GEH** · General & Plastic Surgery
Source: 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.gov