

K163244 truFreeze SystemMay 24, 2017
187 days to decisionK163244 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k163244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Nov 18, 2016
Decision date	May 24, 2017
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	CSA Medical, Inc.
Location	Baltimore, MD, US
Contact	Sherrie Coval-Goldsmith
510(k) history	14 submissions · 14 cleared · 2007-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163244/> 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 June 15, 2026