

K133258 TRUFREEZE SYSTEMJun 19, 2014
239 days to decisionK133258 · Product code: **GEH** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k133258/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Unit, Cryosurgical, Accessories (GEH) |
| Date received | Oct 23, 2013 |
| Decision date | Jun 19, 2014 |
| Days to decision | 239 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | CSA Medical, Inc. |
| Location | Baltimore, MD, US |
| Contact | ELLEN SHEETS, MD, MBA |
| 510(k) history | 14 submissions · 14 cleared · 2007-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133258/> 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