

**K003050 CRYOSURGICAL UNIT AND ACCESSORIES**Dec 26, 2000  
85 days to decisionK003050 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k003050/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent - U                               |
| Submission type       | Traditional  |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received         | Oct 2, 2000  |
| Decision date         | Dec 26, 2000   |
| Days to decision      | 85 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Cryogen, Inc.</b>                  |
| Location       | San Diego, CA, US                     |
| Contact        | CHERYL L SHEA                         |
| 510(k) history | 4 submissions · 3 cleared · 1997-2000 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003050/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 3, 2026