

K982358 HISTOFREEZER DEVICEOct 2, 1998
88 days to decisionK982358 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k982358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Jul 6, 1998
Decision date	Oct 2, 1998
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	OraSure Technologies, Inc.
Location	Bethlehem, PA, US
Contact	R.SAM NIEDBALA
510(k) history	30 submissions · 29 cleared · 1996-2019

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