

K880077 FIBRINOSTICONFeb 9, 1988
29 days to decisionK880077 · Product code: **GHH** · Hematology
Source: <https://www.510kdatabase.net/k880077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Jan 11, 1988
Decision date	Feb 9, 1988
Days to decision	29 days
Third-party review	No

APPLICANT

Company	Organon Teknika Corp.
Location	Mchenry, IL, US
Contact	SHELDON MAZURSKY
510(k) history	130 submissions · 129 cleared · 1980-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k880077/>, 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 May 22, 2026