

K811588 HELENA FETAL-TEK 200 METHODJun 25, 1981
17 days to decisionK811588 · Product code: **JHG** · Chemistry
Source: <https://www.510kdatabase.net/k811588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chromatographic Separation, Lecithin/sphingomyelin Ratio (JHG)
Date received	Jun 8, 1981
Decision date	Jun 25, 1981
Days to decision	17 days
Third-party review	No

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
510(k) history	280 submissions · 280 cleared · 1978-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k811588/> 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 14, 2026