

K802322 MODEL SD-1 DISINTEGRATORNov 10, 1980
48 days to decisionK802322 · Product code: **FFK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k802322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotripter, Electro-hydraulic (FFK)
Date received	Sep 23, 1980
Decision date	Nov 10, 1980
Days to decision	48 days
Third-party review	No

APPLICANT

Company	Northgate Research, Inc.
Location	Mchenry, IL, US
510(k) history	8 submissions · 8 cleared · 1980-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k802322/> 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 July 2, 2026