FDA 510(k) Premarket Notification

K923822 AUTOLITH-IEHL

CLEARED

Jan 28, 1993
182 days to decision

K923822 · Product code: **FFK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k923822/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotriptor, Electro-hydraulic (FFK)
Date received	Jul 30, 1992
Decision date	Jan 28, 1993
Days to decision	182 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Northgate Technologies, Inc.**
Location	Arlington Heights, IL, US
Contact	KENNETH J SIKORA
510(k) history	55 submissions · 55 cleared · 1991-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k923822/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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