FDA 510(k) Premarket Notification

K983326 OMNIFLATOR 7640 MODEL 7-640-00

CLEARED

Feb 5, 1999
136 days to decision

K983326 · Product code: **HIF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k983326/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Sep 22, 1998
Decision date	Feb 5, 1999
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k983326/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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