FDA 510(k) Premarket Notification

K130368 AUTOLITH TOUCH

CLEARED

Nov 15, 2013
274 days to decision

K130368 · Product code: **FFK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k130368/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotriptor, Electro-hydraulic (FFK)
Date received	Feb 14, 2013
Decision date	Nov 15, 2013
Days to decision	274 days
Third-party review	No
Summary / Statement	Summary
Other names	URO TOUCH

APPLICANT

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