

K202813 URO-TOUCH 9 French ProbeJun 14, 2021
263 days to decisionK202813 · Product code: **FFK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k202813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lithotripter, Electro-hydraulic (FFK)
Date received	Sep 24, 2020
Decision date	Jun 14, 2021
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202813/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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