

K162119 UreTron PF Series ProbeAug 29, 2016
28 days to decisionK162119 · Product code: **FFK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k162119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotripter, Electro-hydraulic (FFK)
Date received	Aug 1, 2016
Decision date	Aug 29, 2016
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Med-Sonics Corp.
Location	Erie, PA, US
Contact	JENNIFER RAUTINE
510(k) history	3 submissions · 3 cleared · 2012-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162119/> 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 June 2, 2026