FDA 510(k) Premarket Notification

K162119 UreTron PF Series Probe

CLEARED

Aug 29, 2016
28 days to decision

K162119 · Product code: **FFK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k162119/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lithotriptor, 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