FDA 510(k) Premarket Notification

K161019 Uroview FD

CLEARED

Aug 17, 2016
127 days to decision

K161019 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k161019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Apr 12, 2016
Decision date	Aug 17, 2016
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pausch Medical GmbH**
Location	Erlangen, DE
Contact	Christian Stoian
510(k) history	3 submissions · 3 cleared · 2016-2023