FDA 510(k) Premarket Notification

K180651 Uroview FD II

CLEARED

Apr 12, 2018
30 days to decision

K180651 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k180651/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Mar 13, 2018
Decision date	Apr 12, 2018
Days to decision	30 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