FDA 510(k) Premarket Notification

K173076 CURA 16

CLEARED

Oct 4, 2018
370 days to decision

K173076 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k173076/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Sep 29, 2017
Decision date	Oct 4, 2018
Days to decision	370 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ScintCare CT16

APPLICANT

Company	**Fmi Medical Systems, Inc.**
Location	Solon, OH, US
Contact	Scott LeMaster
510(k) history	2 submissions · 2 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	**FDA 510k Consultants, LLC**
Contact	Paul McFeely

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov