FDA 510(k) Premarket Notification

K181279 Ysio Max

CLEARED

Jun 13, 2018
29 days to decision

K181279 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k181279/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Stationary (KPR)
Date received	May 15, 2018
Decision date	Jun 13, 2018
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medi Cal Solutions, Inc.**
Location	Ann Arbor, MI, US
Contact	Denise Adams
510(k) history	32 submissions · 32 cleared · 2004-2020