FDA 510(k) Premarket Notification

CLEARED

K182317 AMADEO M-DR mini, AMADEO M-AX mini

Sep 24, 2018
28 days to decision

K182317 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k182317/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Aug 27, 2018
Decision date	Sep 24, 2018
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oehm Und Rehbein GmbH**
Location	Rockstock, DE
Contact	Markus Brueggmann
510(k) history	5 submissions · 5 cleared · 2007-2018

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

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