FDA 510(k) Premarket Notification

K213768 Bolt Navigation System

CLEARED

Dec 1, 2022
365 days to decision

K213768 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k213768/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Dec 1, 2021
Decision date	Dec 1, 2022
Days to decision	365 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Circinus Medical Technology, LLC**
Location	Boulder, CO, US
Contact	Patrick West
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Alex Cadotte

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