FDA 510(k) Premarket Notification

K050866 CENTRION 500 C-ARM SYSTEM

CLEARED

Apr 27, 2005
22 days to decision

K050866 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k050866/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Apr 5, 2005
Decision date	Apr 27, 2005
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osteosys Co.,Ltd**
Location	Brookeville, MD, US
Contact	T. WHIT ATHEY
510(k) history	1 submissions · 1 cleared · 2005-2005