FDA 510(k) Premarket Notification

K800639 ORBITOR

CLEARED

May 14, 1980
51 days to decision

K800639 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k800639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Mar 24, 1980
Decision date	May 14, 1980
Days to decision	51 days
Third-party review	No

APPLICANT

Company	**Philips Medical Systems (Cleveland), Inc.**
Location	Mchenry, IL, US
510(k) history	190 submissions · 190 cleared · 1977-2017

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k800639/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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