FDA 510(k) Premarket Notification

K852331 SYS, ANGIOGRAPHIC, SINGLE-OR BI-PLANE RADIOGRAPHIC

CLEARED

Aug 1, 1986
427 days to decision

K852331 · Product code: **IZI** · Radiology
Source: https://www.510kdatabase.net/k852331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	May 31, 1985
Decision date	Aug 1, 1986
Days to decision	427 days
Third-party review	No

APPLICANT

Company	**Scholten Surgical Instruments, Inc.**
Location	Redwood City, CA, US
Contact	JACOBUS SCHOLTEN
510(k) history	8 submissions · 8 cleared · 1985-2007