FDA 510(k) Premarket Notification

K963913 MD100 & MM150

CLEARED

Oct 8, 1997
373 days to decision

K963913 · Product code: **EAM** · Radiology
Source: https://www.510kdatabase.net/k963913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screen, Intensifying, Radiographic (EAM)
Date received	Sep 30, 1996
Decision date	Oct 8, 1997
Days to decision	373 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Konica Medical Corp.**
Location	New York, NY, US
Contact	RUSSELL D MUNVES
510(k) history	12 submissions · 12 cleared · 1990-1999