K974423 ULTRA-VISION MAMMOGRAPHY DETAIL, ULTRA-VISION MAMMOGRAPHY FAST DETAIL

CLEARED

Dec 22, 1997
28 days to decision

K974423 · Product code: **EAM** · Radiology
Source: https://www.510kdatabase.net/k974423/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screen, Intensifying, Radiographic (EAM)
Date received	Nov 24, 1997
Decision date	Dec 22, 1997
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sterling Diagnostic Imaging, Inc.**
Location	Newark, DE, US
Contact	JEAN E BARLETT
510(k) history	7 submissions · 7 cleared · 1996-1998