FDA 510(k) Premarket Notification

K905748 MAMEX DC AMI SL12/MG15

CLEARED

Mar 7, 1991
71 days to decision

K905748 · Product code: **IZH** · Radiology
Source: https://www.510kdatabase.net/k905748/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Dec 26, 1990
Decision date	Mar 7, 1991
Days to decision	71 days
Third-party review	No

APPLICANT

Company	**Soredex, Inc.**
Location	Sf-00511 Helsinki Finland, FI
Contact	ENSIO KOSKENNURMI
510(k) history	1 submissions · 1 cleared · 1991-1991