FDA 510(k) Premarket Notification

K971347 MEDISURF

CLEARED

Jul 3, 1997
84 days to decision

K971347 · Product code: **LMD** · Radiology
Source: https://www.510kdatabase.net/k971347/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Digital Image Communications, Radiological (LMD)
Date received	Apr 10, 1997
Decision date	Jul 3, 1997
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**International Regulatory Consultants**
Location	Efrat, Israel, IL
Contact	ELI M ORBACH
510(k) history	5 submissions · 5 cleared · 1994-1998