FDA 510(k) Premarket Notification

K990192 BIOPSY-DIGIT

CLEARED

Mar 12, 1999
50 days to decision

K990192 · Product code: **IZH** · Radiology
Source: https://www.510kdatabase.net/k990192/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Jan 21, 1999
Decision date	Mar 12, 1999
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sitco, Inc.**
Location	Mundelein, IL, US
Contact	ROBERT H MCCARTHY
510(k) history	4 submissions · 4 cleared · 1995-1999