FDA 510(k) Premarket Notification

K030363 ORG@NIZER, MODEL VERSION 3.0

CLEARED

Mar 27, 2003
51 days to decision

K030363 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k030363/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 4, 2003
Decision date	Mar 27, 2003
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ebit Sanita, S.P.A.**
Location	Indianpolis, IN, US
Contact	COLLEEN DENSMORE
510(k) history	1 submissions · 1 cleared · 2003-2003