FDA 510(k) Premarket Notification

K980873 KONICA DIRECT DIGITIZER REGIUS MODEL 330

CLEARED

Jun 19, 1998
105 days to decision

K980873 · Product code: **LMA** · Radiology
Source: https://www.510kdatabase.net/k980873/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digitizer, Image, Radiological (LMA)
Date received	Mar 6, 1998
Decision date	Jun 19, 1998
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Konica Corp.**
Location	New York, NY, US
Contact	RUSSELL D MUNVES
510(k) history	5 submissions · 5 cleared · 1992-1999