FDA 510(k) Premarket Notification

K002258 ULTRAGUIDE CT-GUIDE 1010

CLEARED

Aug 8, 2000
14 days to decision

K002258 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k002258/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jul 25, 2000
Decision date	Aug 8, 2000
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Ultraguide , Ltd.**
Location	Hasbrouck Heights, NJ, US
Contact	GEORGE MYERS
510(k) history	6 submissions · 6 cleared · 1998-2002