FDA 510(k) Premarket Notification

K963789 DTX-100 BONE DENSITOMETER

CLEARED

Jul 14, 1997
297 days to decision

K963789 · Product code: **KGI** · Radiology
Source: https://www.510kdatabase.net/k963789/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Densitometer, Bone (KGI)
Date received	Sep 20, 1996
Decision date	Jul 14, 1997
Days to decision	297 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osteometer Meditech A/S**
Location	Dallas, TX, US
Contact	BERT HUDSON
510(k) history	2 submissions · 2 cleared · 1997-1997