FDA 510(k) Premarket Notification

K010883 TERATECH MODEL 8EC4 ENDOCAVITY SMART PROBE

CLEARED

Apr 6, 2001
14 days to decision

K010883 · Product code: **ITX** · Radiology
Source: https://www.510kdatabase.net/k010883/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Mar 23, 2001
Decision date	Apr 6, 2001
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Teratech Corp.**
Location	Saratoga, CA, US
Contact	CHARLES F HOTTINGER
510(k) history	17 submissions · 17 cleared · 1999-2015