FDA 510(k) Premarket Notification

K885075 ABIOMED PERIOTEMP(TM) PROBE

CLEARED

Feb 13, 1989
67 days to decision

K885075 · Product code: **EIL** · Dental
Source: https://www.510kdatabase.net/k885075/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauge, Depth, Instrument, Dental (EIL)
Date received	Dec 8, 1988
Decision date	Feb 13, 1989
Days to decision	67 days
Third-party review	No

APPLICANT

Company	**Abiomed, Inc.**
Location	Danvers, MA, US
Contact	PARAM I SINGH
Website	http://www.abiomed.com/
510(k) history	19 submissions · 17 cleared · 1989-2025

Abiomed, Inc. develops innovative cardiovascular devices focused on native heart recovery. Founded in 1981, the company specializes in percutaneous heart pump technology and related support systems. Now part of Johnson & Johnson, Abiomed operates with a manufacturing facility in Danvers, Massachusetts. Abiomed has received FDA 510(k) clearances from total submissions since 1989. Cardiovascular devices represent 84% of the company's regulatory portfolio. The company remains active, with the latest clearance in 2025, demonstrating continued innovation and market presence. T...