FDA 510(k) Premarket Notification

# K911643 ABIODENT PERIOTEMP(R) SYSTEM

**CLEARED**

Jul 9, 1991
88 days to decision

K911643 · Product code: **EIL** · Dental
Source: https://www.510kdatabase.net/k911643/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gauge, Depth, Instrument, Dental (EIL) |
| Date received | Apr 12, 1991 |
| Decision date | Jul 9, 1991 |
| Days to decision | 88 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Abiomed, Inc.** |
| Location | Danvers, MA, US |
| Contact | BRUCE J SHOOK |
| 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...