FDA 510(k) Premarket Notification

CLEARED

K900574 ABIOMED BODY LEAD ANALYZER MODEL 200/20

Mar 15, 1990
36 days to decision

K900574 · Product code: **JAO** · Radiology
Source: https://www.510kdatabase.net/k900574/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scanner, Fluorescent (JAO)
Date received	Feb 7, 1990
Decision date	Mar 15, 1990
Days to decision	36 days
Third-party review	No

APPLICANT

Company	**Abiomed, Inc.**
Location	Danvers, MA, US
Contact	FREDRIC L MILDER
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...