FDA 510(k) Premarket Notification

K943338 BIOSENSOR BIDOP VASCULAR TEST SYSTEM

CLEARED

Apr 12, 1996
640 days to decision

K943338 · Product code: **JAF** · Radiology
Source: https://www.510kdatabase.net/k943338/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Nonfetal (JAF)
Date received	Jul 12, 1994
Decision date	Apr 12, 1996
Days to decision	640 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Biosensor Corp.**
Location	Walker, MI, US
Contact	DARREN D DERSHEM
510(k) history	10 submissions · 10 cleared · 1983-1999