FDA 510(k) Premarket Notification

K810363 EAR OXIMETER

CLEARED

Feb 27, 1981
16 days to decision

K810363 · Product code: **DPZ** · Anesthesiology
Source: https://www.510kdatabase.net/k810363/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Ear (DPZ)
Date received	Feb 11, 1981
Decision date	Feb 27, 1981
Days to decision	16 days
Third-party review	No

APPLICANT

Company	**Bio-Tek Instruments, Inc.**
Location	Mchenry, IL, US
510(k) history	37 submissions · 35 cleared · 1980-1997

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k810363/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 21, 2026