FDA 510(k) Premarket Notification

K964821 COVEROX SHEATH MODELS NUMBER PS65, PS67, EPS65 AND EPS67

CLEARED

Jul 16, 1997
226 days to decision

K964821 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k964821/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Dec 2, 1996
Decision date	Jul 16, 1997
Days to decision	226 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ventrex, Inc.**
Location	Portland, ME, US
Contact	ROBERT B GUTHRIE
510(k) history	5 submissions · 5 cleared · 1992-2006