FDA 510(k) Premarket Notification

K913013 TCPO2 9260 MODULE - SYSTEM ATHENA

CLEARED

May 3, 1994
1030 days to decision

K913013 · Product code: **LKD** · Anesthesiology
Source: https://www.510kdatabase.net/k913013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Carbon-dioxide, Cutaneous (LKD)
Date received	Jul 8, 1991
Decision date	May 3, 1994
Days to decision	1030 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**S & W Medico Teknik**
Location	Walker, MI, US
Contact	MORTEN NIELSON
510(k) history	46 submissions · 46 cleared · 1984-1995