FDA 510(k) Premarket Notification

K003180 HOMMED OBSERVER, MODEL I

CLEARED

Jun 28, 2001
260 days to decision

K003180 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k003180/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Oct 11, 2000
Decision date	Jun 28, 2001
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hommed, LLC**
Location	Houston, TX, US
Contact	TOMMIE J MORGAN
510(k) history	8 submissions · 8 cleared · 2000-2004