FDA 510(k) Premarket Notification

K001306 STETHOS, MODEL STXXYYZZ OR 001 XXX, STETHOS LINK, MODEL SLXXYYZZ OR 002 XXX

CLEARED

Jul 20, 2000
86 days to decision

K001306 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k001306/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Apr 25, 2000
Decision date	Jul 20, 2000
Days to decision	86 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Andromed, Inc.**
Location	St.Laurent, Quebec, CA
Contact	JEAN DUMAS
510(k) history	5 submissions · 5 cleared · 2000-2005