FDA 510(k) Premarket Notification

K960625 SPREADABLE SHEATH INTRODUCER SET

CLEARED

Aug 8, 1996
177 days to decision

K960625 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k960625/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Feb 13, 1996
Decision date	Aug 8, 1996
Days to decision	177 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Neostar Medical Technologies, Inc.**
Location	New Brunswick, NJ, US
Contact	DAVID W WEAVER III
510(k) history	4 submissions · 4 cleared · 1995-1996