FDA 510(k) Premarket Notification

K913803 INTRALUMINAL ARTERY STRIPPER

CLEARED

Apr 24, 1992
242 days to decision

K913803 · Product code: **DWX** · Cardiovascular
Source: https://www.510kdatabase.net/k913803/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stripper, Artery, Intraluminal (DWX)
Date received	Aug 26, 1991
Decision date	Apr 24, 1992
Days to decision	242 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Omni-Tract Surgical, Div. Minn. Scientific, Inc.**
Location	St. Paul, MN, US
Contact	DALE STULL
510(k) history	4 submissions · 4 cleared · 1992-2000