FDA 510(k) Premarket Notification

K833554 MATERIAL ADDITION LEXAN & K-RESIN

CLEARED

Mar 12, 1984
159 days to decision

K833554 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k833554/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Oct 5, 1983
Decision date	Mar 12, 1984
Days to decision	159 days
Third-party review	No

APPLICANT

Company	**Procedure Products, Inc.**
Location	Mchenry, IL, US
510(k) history	16 submissions · 16 cleared · 1981-2017