FDA 510(k) Premarket Notification

K801394 CARDIOPULMONARY BYPASS PUMP TUBING

CLEARED

Jun 30, 1980
17 days to decision

K801394 · Product code: **DWE** · Cardiovascular
Source: https://www.510kdatabase.net/k801394/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubing, Pump, Cardiopulmonary Bypass (DWE)
Date received	Jun 13, 1980
Decision date	Jun 30, 1980
Days to decision	17 days
Third-party review	No

APPLICANT

Company	**Texas Medical Products, Inc.**
Location	Mchenry, IL, US
510(k) history	30 submissions · 30 cleared · 1980-1989