FDA 510(k) Premarket Notification

K831750 PM-3

CLEARED

Jul 26, 1983
55 days to decision

K831750 · Product code: **DXS** · Cardiovascular
Source: https://www.510kdatabase.net/k831750/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauge, Pressure, Coronary, Cardiopulmonary Bypass (DXS)
Date received	Jun 1, 1983
Decision date	Jul 26, 1983
Days to decision	55 days
Third-party review	No

APPLICANT

Company	**Delta Medical Industries**
Location	Mchenry, IL, US
510(k) history	27 submissions · 27 cleared · 1976-1984