FDA 510(k) Premarket Notification

K911632 CAPIOX(R) BUBBLE TRAP

CLEARED

Jul 9, 1991
89 days to decision

K911632 · Product code: **KRL** · Cardiovascular
Source: https://www.510kdatabase.net/k911632/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector, Bubble, Cardiopulmonary Bypass (KRL)
Date received	Apr 11, 1991
Decision date	Jul 9, 1991
Days to decision	89 days
Third-party review	No

APPLICANT

Company	**Terumo Medical Corp.**
Location	Elkton, MD, US
Contact	GEORGE S MOMODA
510(k) history	143 submissions · 143 cleared · 1980-2011