FDA 510(k) Premarket Notification

K812338 PREZA-PAK II, ARTERIAL BLOOD SAMPLING SY

CLEARED

Sep 23, 1981
36 days to decision

K812338 · Product code: **CBT** · Anesthesiology
Source: https://www.510kdatabase.net/k812338/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arterial Blood Sampling Kit (CBT)
Date received	Aug 18, 1981
Decision date	Sep 23, 1981
Days to decision	36 days
Third-party review	No

APPLICANT

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