FDA 510(k) Premarket Notification

K840674 SENSIBEAD EIA IGE KIT

CLEARED

Apr 4, 1984
49 days to decision

K840674 · Product code: **DGC** · Immunology
Source: https://www.510kdatabase.net/k840674/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Feb 15, 1984
Decision date	Apr 4, 1984
Days to decision	49 days
Third-party review	No

APPLICANT

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