FDA 510(k) Premarket Notification

K913306 BONE-TEMNO/STERNUM-TEMNO

CLEARED

Nov 1, 1991
99 days to decision

K913306 · Product code: **LWE** · General Hospital
Source: https://www.510kdatabase.net/k913306/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Marrow Collection/transfusion Kit (LWE)
Date received	Jul 25, 1991
Decision date	Nov 1, 1991
Days to decision	99 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Proact, Ltd.**
Location	State College, PA, US
Contact	JOSEPH M LOONEY
510(k) history	5 submissions · 5 cleared · 1990-1994