FDA 510(k) Premarket Notification

K981823 OPERATING ROOM TOWELS

CLEARED

Aug 11, 1998
81 days to decision

K981823 · Product code: **KKX** · General Hospital
Source: https://www.510kdatabase.net/k981823/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drape, Surgical (KKX)
Date received	May 22, 1998
Decision date	Aug 11, 1998
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Baldur Systems Corp.**
Location	Hayward, CA, US
Contact	STEVE WOODY
510(k) history	6 submissions · 6 cleared · 1989-1998