FDA 510(k) Premarket Notification

K991591 BIOTHANE PATIENT RESTRAINT

CLEARED

Jul 29, 1999
83 days to decision

K991591 · Product code: **FMQ** · General Hospital
Source: https://www.510kdatabase.net/k991591/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Restraint, Protective (FMQ)
Date received	May 7, 1999
Decision date	Jul 29, 1999
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Bioplastics**
Location	N. Ridgeville, OH, US
Contact	CLAIRE BORON
510(k) history	1 submissions · 1 cleared · 1999-1999