

K991591 BIOTHANE PATIENT RESTRAINTJul 29, 1999
83 days to decisionK991591 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991591/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 4, 2026