

K950755 FLEXMATE K500Oct 5, 1995
230 days to decisionK950755 · Product code: **BXB** · Physical Medicine
Source: <https://www.510kdatabase.net/k950755/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Exerciser, Powered (BXB)
Date received	Feb 17, 1995
Decision date	Oct 5, 1995
Days to decision	230 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Breg, Inc.
Location	Costa Mesa, CA, US
Contact	BARBER
510(k) history	16 submissions · 16 cleared · 1991-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950755/> 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 June 28, 2026