

K090722 SHAPE-HF CARDIOPULMONARY EXERCISE TESTING SYSTEMMar 31, 2009
12 days to decisionK090722 · Product code: **BTY** · Anesthesiology
Source: <https://www.510kdatabase.net/k090722/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Predicted Values, Pulmonary Function (BTY)
Date received	Mar 19, 2009
Decision date	Mar 31, 2009
Days to decision	12 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Shape Medical Systems, Inc.
Location	Minneapolis, MN, US
Contact	CLARENCE JOHNSON
510(k) history	2 submissions · 2 cleared · 2009-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090722/> 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 May 24, 2026