

K981451 ARGOMEDICAL BIPOLAR SYSTEMAug 21, 1998
121 days to decisionK981451 · Product code: **KWL** · Orthopedic
Source: <https://www.510kdatabase.net/k981451/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	Apr 22, 1998
Decision date	Aug 21, 1998
Days to decision	121 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Stelkast Company
Location	Pittsburgh, PA, US
Contact	DONALD A STEVENS
510(k) history	40 submissions · 37 cleared · 1994-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981451/> 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 18, 2026