

K931429 COOL CUTApr 29, 1994
403 days to decisionK931429 · Product code: **HWE** · Orthopedic
Source: <https://www.510kdatabase.net/k931429/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Surgical, Orthopedic, Ac-powered Motor And Accessory/attachment (HWE)
Date received	Mar 22, 1993
Decision date	Apr 29, 1994
Days to decision	403 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mitab
Location	Sweden, SE
Contact	ANNETTE MATTSSON
510(k) history	1 submissions · 1 cleared · 1994-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k931429/> 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 22, 2026