FDA 510(k) Premarket Notification

K030838 WARTNER PRO

CLEARED

Jun 27, 2003
102 days to decision

K030838 · Product code: **GEH** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k030838/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Mar 17, 2003
Decision date	Jun 27, 2003
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Wartner Medical Products**
Location	Brampton, Ontario, CA
Contact	NANCY LUM-WILSON
510(k) history	3 submissions · 3 cleared · 2000-2003

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k030838/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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