

**K910491 WALLACH COLD SOAKER**May 21, 1991  
105 days to decisionK910491 · Product code: **GEH** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k910491/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Cryosurgical, Accessories (GEH)
Date received	Feb 5, 1991
Decision date	May 21, 1991
Days to decision	105 days
Third-party review	No

**APPLICANT**

---

Company	<b>Wallach Surgical Devices, Inc.</b>
Location	Walker, MI, US
Contact	VINCENT FRAZZETTA
510(k) history	27 submissions · 27 cleared · 1981-2002

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k910491/>, Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 20, 2026