

**K945861 BERGEN 710 ESU**Mar 1, 1995  
90 days to decisionK945861 · Product code: **HAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k945861/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Electrosurgical (HAM)
Date received	Dec 1, 1994
Decision date	Mar 1, 1995
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Bergen Mfg.</b>
Location	New Port Richey, FL, US
Contact	ROGER OOSTEN
510(k) history	4 submissions · 4 cleared · 1986-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945861/> 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 July 4, 2026