

**K002013 OMNIPOINT**Sep 29, 2000  
88 days to decisionK002013 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k002013/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jul 3, 2000
Decision date	Sep 29, 2000
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Advanced Surgical Concepts (Asc)</b>
Location	North Attleboro, MA, US
Contact	MARY MCNAMARA-CULLINANE
510(k) history	4 submissions · 4 cleared · 1999-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k002013/> 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 1, 2026