

**K980301 IP-16**Mar 24, 1998  
56 days to decisionK980301 · Product code: **BTA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k980301/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Portable, Aspiration (manual Or Powered) (BTA)
Date received	Jan 27, 1998
Decision date	Mar 24, 1998
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Servizi Medico Estetici Italinai Srl.</b>
Location	Casale Monferrato (AI), IT
Contact	JAMES E LENICK
510(k) history	2 submissions · 2 cleared · 1997-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980301/> 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