

K984355 POINT SETTERApr 1, 1999
115 days to decisionK984355 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k984355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 7, 1998
Decision date	Apr 1, 1999
Days to decision	115 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mitaka USA, Inc.
Location	Park City, UT, US
Contact	MAX STURGIS
510(k) history	2 submissions · 2 cleared · 1999-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984355/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026