

K100045 OCTOJun 25, 2010
168 days to decisionK100045 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k100045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jan 8, 2010
Decision date	Jun 25, 2010
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dalim Surgnet Corporation
Location	Pittsburgh, PA, US
Contact	PETER CHUNG
510(k) history	2 submissions · 2 cleared · 2010-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100045/> 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 18, 2026