

**K011183 OMNIPOINT HAND AND INSTRUMENT ACCESS
DEVICE**Jun 15, 2001
58 days to decisionK011183 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k011183/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Apr 18, 2001
Decision date	Jun 15, 2001
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011183/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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