

K160801 Well Lead Extraction BagNov 29, 2016
251 days to decisionK160801 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k160801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Mar 23, 2016
Decision date	Nov 29, 2016
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Well Lead Medical Co., Ltd.
Location	Apollo Beach, FL, US
Contact	HAN GUANG YUAN
510(k) history	17 submissions · 17 cleared · 2009-2025

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