

K161228 Radiance Ultra Series ZeroWire EmbeddedMay 26, 2016
24 days to decisionK161228 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	May 2, 2016
Decision date	May 26, 2016
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nds Surgical Imaging, LLC
Location	San Jose, CA, US
Contact	Jim Leng
510(k) history	4 submissions · 4 cleared · 2015-2022

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