FDA 510(k) Premarket Notification

K191930 7 mm Extended Length Endoscope

CLEARED

Apr 15, 2020
271 days to decision

K191930 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191930/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jul 19, 2019
Decision date	Apr 15, 2020
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Maquet Cardiovascular, LLC**
Location	San Jose, CA, US
Contact	Mark Dinger
510(k) history	14 submissions · 14 cleared · 2008-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k191930/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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