FDA 510(k) Premarket Notification

K161720 Standard Clamp

CLEARED

Oct 24, 2016
124 days to decision

K161720 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k161720/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jun 22, 2016
Decision date	Oct 24, 2016
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Standard Bariatrics**
Location	Cincinnati, OH, US
Contact	Alison Sathe
510(k) history	10 submissions · 10 cleared · 2016-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k161720/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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