

K160969 ShineMed Reloadable Open Cutting Stapler, ShineMed Curved Intraluminal Cutting Stapler

Dec 12, 2016
250 days to decision

K160969 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k160969/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Apr 6, 2016
Decision date	Dec 12, 2016
Days to decision	250 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shinemed, LLC
Location	Winter Park, FL, US
Contact	ROGELIO A. INSIGNARES
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k160969/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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