

K162710 Single Use Circular Stapler, Single Use Hemorrhoidal Circular Stapler, Single Patient Use Linear Stapler and Reload, Single Patient Use Linear Cutter and Reload, Single Patient Use Endo Cutter and Reload, Single Patient Use Transverse Cutter and Reload

Feb 9, 2017
134 days to decision

K162710 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k162710/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Sep 28, 2016
Decision date	Feb 9, 2017
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tgs Medical Co., Ltd.
Location	Suzhou, CN
Contact	Hua Cao
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k162710/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026