

K190677 EndoClotJan 29, 2021
686 days to decisionK190677 · Product code: **QAU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Device For Endoscopic Gastrointestinal Use (QAU)
Date received	Mar 15, 2019
Decision date	Jan 29, 2021
Days to decision	686 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Endoclot Plus Co., Ltd.
Location	Suzhou, CN
Contact	Huihui Xie
510(k) history	3 submissions · 3 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	Medwheat (Shanghai) Medical Technology Co. , Ltd.
Contact	Jonathan Hu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190677/> 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 May 27, 2026