FDA 510(k) Premarket Notification

K190677 EndoClot

CLEARED

Jan 29, 2021
686 days to decision

K190677 · Product code: **QAU** · General & Plastic Surgery
Source: 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