

K173004 SB Soft Hood - Straight type, SB Soft Hood - Undercut typeMay 8, 2018
223 days to decisionK173004 · Product code: **FDS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k173004/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Sep 27, 2017
Decision date	May 8, 2018
Days to decision	223 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sumitomo Bakelite Co., Ltd.
Location	Tokyo, JP
Contact	Shiro Agehama
510(k) history	4 submissions · 4 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	Mic International Corp.
Contact	Izumi Maruo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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