

**K250452 CoralWell™ Single-use Ureteral Access Sheath
(NS-0835B, NS-0840B, NS-0845B, NS-0855B, NS-0935B,
NS-0940B, NS-0945B, NS-0955B, NS-1035B, NS-1040B,
NS-1045B, NS-1055B, NS-1135B, NS-1140B, NS-1145B,
NS-1155B, NS-1235B, NS-1240B, NS-1245B, NS-1255B,
NS-1335B, NS-1340B, NS-1345B, NS-1355B, NS-1435B,
NS-1440B, NS-1445B, NS-1455B)**

Jun 2, 2025
104 days to decision

K250452 · Product code: FED · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250452/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Feb 18, 2025
Decision date	Jun 2, 2025
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	MacroLux Medical Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Ye Linbin
510(k) history	6 submissions · 6 cleared · 2024-2026
