

**K242571 Secret Line up (FC1938E80 FC1950E90 FC1960E100
 FC1970E120 FC1990E150 FC19100E150 FC19100E280
 FC19100E420 FC2038E80 FC2050E90 FC2060E100 FC2070E120
 FC2090E150 FC20100E170 FC2138G80 FC2150G90 FC2160G100
 FC2170G120 FC2190G150 FC21100G170 FCL18100C160
 FCL1938E80 FCL1950E90 FCL1960E100 FCL1970E120
 FCL1990E150 FCL19100E160 FCL2138G80 FCL2150G90
 FCL2160G100 FCL2170G120 FCL2190G150 FCL21100G160
 FCRL1870C162 FCRL18100C185 FCRL1970E162
 FCRL19100E185 FCHL1960E90 FCHL1970E120 FCHL19100E160
 FCW1938**

Sep 27, 2024
 29 days to decision

K242571 · Product code: **NEW** · General & Plastic Surgery
 Source: <https://www.510kdatabase.net/k242571/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Aug 29, 2024
Decision date	Sep 27, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hyundae Meditech Co., Ltd.
Location	Wonju-Si, KR
Contact	Oh Ju-in
510(k) history	2 submissions · 2 cleared · 2024-2024
