FDA 510(k) Premarket Notification

K213338 CORE-CLIP

CLEARED

Jun 23, 2022
259 days to decision

K213338 · Product code: **PKL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k213338/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Oct 7, 2021
Decision date	Jun 23, 2022
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Incore Co., Ltd.**
Location	Daegu, KR
Contact	Jae-Hun Lee
510(k) history	6 submissions · 6 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	**KMC, Inc.**
Contact	Seon-mi Kim

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