FDA 510(k) Premarket Notification

CLEARED

K220549 MINT Product Family (Including MINT, MINT Lift, and MINT-I Sutures), MINT Lift ML 1043, MINT Lift ML 1013, MINT Lift 1019, MINT Lift Mini 1014

Mar 7, 2023
375 days to decision

K220549 · Product code: **NEW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220549/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Feb 25, 2022
Decision date	Mar 7, 2023
Days to decision	375 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hans Biomed Corporation**
Location	Brea, CA, US
Contact	Lucy Choi
510(k) history	4 submissions · 4 cleared · 2013-2023

REGULATORY CONSULTANT

Consulting firm	**Emergo by UL**
Contact	Sarah Fitzgerald

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