FDA 510(k) Premarket Notification

K242946 HESTIA (L200-A)

CLEARED

Oct 3, 2025
373 days to decision

K242946 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242946/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 25, 2024
Decision date	Oct 3, 2025
Days to decision	373 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Senbitec Co., Ltd.**
Location	Anyang-Si, KR
Contact	Ga Hee Han
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Mtech Group, LLC**
Contact	Dave Kim

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