K231495 The Evolve System with the Transform Applicator

CLEARED

Oct 13, 2023
143 days to decision

K231495 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k231495/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	May 23, 2023
Decision date	Oct 13, 2023
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inmode , Ltd.**
Location	Yokneam, IL
Contact	Suhair Francis
510(k) history	15 submissions · 15 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice M. Hogan

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

CLINICAL EVIDENCE - NCT05398159

Trim II for Noninvasive Lipolysis and Circumference Reduction of Abdomen.

Status	Completed
Enrollment	75 patients (actual)
Study sites	5 sites
Condition studied	Circumference Reduction of Abdomen
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Oct 30, 2022
Sponsor	InMode MD Ltd. (Industry)

Primary outcome

Evaluation of Change in Abdomen Circumference Using Tape Measurements in cm at the 3 Months Follow-up Visit Comparing to Baseline.

Secondary outcome

Percentage of Participants With Baseline and 3 Month Abdomen Photographs Correctly Identified by Two Blind Evaluators

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05398159