K191749 TIGR Matrix Surgical Mesh, TIGR Surgical Mesh

CLEARED

Mar 26, 2020
269 days to decision

K191749 · Product code: **OWT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191749/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Abdominal Hernia (OWT)
Date received	Jul 1, 2019
Decision date	Mar 26, 2020
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Novus Scientific AB**
Location	Uppsala, SE
Contact	Thomas Engstrom
510(k) history	2 submissions · 2 cleared · 2017-2020

REGULATORY CONSULTANT

Consulting firm	**Cygnus Regulatory, LLC**
Contact	Loredana M Guseila

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

CLINICAL EVIDENCE - NCT01622725

Primary and Secondary Ventral Hernia Repair Using Long-term Resorbable Versus Non-resorbable Large Pore Synthetic Mesh.

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	95 patients (actual)
Study sites	6 sites
Condition studied	Primary and Secondary Ventral Hernia
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Dec 31, 2023
Sponsor	University Hospital, Ghent (Other)

Primary outcome

Recurrence rate at 3 years post-surgery.

Secondary outcome

Wound Morbidity 4 weeks post-surgery.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT01622725