

K250109 TYBR Collagen GelJun 6, 2025
141 days to decisionK250109 · Product code: **OWY** · Orthopedic
Source: <https://www.510kdatabase.net/k250109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement Of Tendon (OWY)
Date received	Jan 16, 2025
Decision date	Jun 6, 2025
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tybr Health
Location	Houston, TX, US
Contact	Tim Keane
Website	https://www.tybrhealth.com/
510(k) history	1 submissions · 1 cleared · 2025-2025

Tybr Health develops orthopedic surgical solutions focused on soft tissue healing and mobility preservation. The company is based in Houston, Texas, with an FDA-registered facility in the same location. Tybr Health has received FDA 510(k) clearance from total submission. The company's regulatory activity began in 2025, with its cleared device falling within the orthopedic category. This recent clearance demonstrates active engagement in the medical device market. The company's cleared device, TYBR Collagen Gel, is designed to optimize post-operative tendon healing by crea...

REGULATORY CONSULTANT

Consulting firm	Bruder Consulting & Venture Group
Contact	Scott Bruder

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