

K210604 Intellihab SystemJun 3, 2021
94 days to decisionK210604 · Product code: **IPF** · Physical Medicine
Source: <https://www.510kdatabase.net/k210604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Mar 1, 2021
Decision date	Jun 3, 2021
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cymedica Orthopedics, Inc.
Location	Scottsdale, AZ, US
Contact	Kereshmeh Shahriari
510(k) history	5 submissions · 5 cleared · 2015-2023

CLINICAL EVIDENCE - NCT04128618

Evaluation of a Home-based NMES Therapy for Knee Osteoarthritis Pain

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	159 patients (actual)
Study sites	2 sites
Condition studied	Knee Osteoarthritis
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Triple
Completion date	Nov 24, 2020
Sponsor	CyMedica Orthopedics, Inc (Industry)

Primary outcome

Knee pain using VAS scale (Visual Analog Scale)

Secondary outcome

Timed Up & Go (TUG)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04128618