

K192234 ActiPatchJan 31, 2020
165 days to decisionK192234 · Product code: **PQY** · Physical Medicine
Source: <https://www.510kdatabase.net/k192234/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nonthermal Shortwave Therapy Device Indicated For Over The Counter Use For The Treatment Of Pain (PQY)
Date received	Aug 19, 2019
Decision date	Jan 31, 2020
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bioelectronics Corporation
Location	Frederick, MD, US
Contact	Sree N. Koneru
510(k) history	3 submissions · 3 cleared · 2017-2020

CLINICAL EVIDENCE - NCT03542955

Pulse Shortwave Therapy in Cervical Osteoarthritis

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	180 patients (actual)
Study sites	1 site
Condition studied	Cervical Osteoarthritis
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jul 30, 2019
Sponsor	BioElectronics Corporation (Industry)

Primary outcome

Neck Disability Index (NDI)

Secondary outcome

Visual Analog Scale (VAS)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03542955