

**K182090 AposTherapy System**Nov 16, 2018  
106 days to decisionK182090 · Product code: **QDT** · Physical Medicine  
Source: <https://www.510kdatabase.net/k182090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoe With Adjustable Sole Units (QDT)
Date received	Aug 2, 2018
Decision date	Nov 16, 2018
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>Apos Medical Assets , Ltd.</b>
Location	Tel Aviv, IL
Contact	Cliff Bleustein
510(k) history	1 submissions · 1 cleared · 2018-2018

**REGULATORY CONSULTANT**

Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Janice Hogan

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

**CLINICAL EVIDENCE - NCT00457132****The Effect of Neuromuscular Training on Osteoarthritis: A Comparative Prospective Randomized Study**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	60 patients (estimated)
Study sites	1 site
Condition studied	Knee Osteoarthritis
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Feb 1, 2006
Sponsor	Assaf-Harofeh Medical Center (Other_gov)

**Primary outcome**

Western Ontario and McMaster Osteoarthritis Index (WOMAC)

**Secondary outcome**

SF-36 health survey

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT00457132](https://clinicaltrials.gov/study/NCT00457132)