November 16, 2018

APOS Medical Assets Ltd.
% Janice Hogan
Partner
Hogan Lovells U.S. LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K182090
Trade/Device Name: AposTherapy System
Regulation Number: 21 CFR 890.3475
Regulation Name: Limb Orthosis
Regulatory Class: Class I
Product Code: QDT
Dated: October 25, 2018
Received: October 25, 2018

Dear Janice Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182090

Device Name
AposTherapy System

Indications for Use *(Describe)*
The AposTherapy System is intended to be used by trained professionals for adjusting the distribution of weight/force(s) that is being applied to a lower limb. The AposTherapy System is intended for patients with knee osteoarthritis, to help temporarily reduce knee pain and improve lower extremity function during activities of daily living.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY – K182090

APOS Medical Assets Ltd.'s AposTherapy System

Submitter

APOS Medical Assets Ltd.
7 Hapelech Street
Tel-Aviv, Israel 6816727

Phone: 917-993-2911

Contact Person: Cliff Bleustein, MD, MBA, Chief Medical Officer

Date: November 16, 2018

Name of Device: AposTherapy System

Common or Usual Name: Orthosis, Shoe with adjustable sole units

Classification Name: 21 C.F.R. 890.3475, *Limb orthosis*

Regulatory Class: Class I

Product Code: QDT, *Shoe with adjustable sole units*

Predicate Device: Substantially equivalent to 21 C.F.R. 890.3475

Device Description

The AposTherapy System consists of a pair of shoe-like uppers with two convex units (Pertupods) on the sole of each shoe, a screw fixation mechanism for securely attaching the Pertupod to the track and, if required, soft spacers, weight discs, hard spacers, and wedge spacers. Legally marketed gait analysis software may be used by practitioners to help inform their calibration of the biomechanical device, but the software is not supplied with the device.

The device is worn over socks, so it has no direct contact with the patient. Based on a preliminary evaluation of pain, function, and quality of life, a personalized therapy program is created to meet the patient's treatment needs using the personally calibrated device. Practitioners may use basic, legally marketed gait analysis software (not provided with the device) to collect measurements from various movements (*e.g.,* velocity, step length, single limb support) as part of the treatment program. The patient's progress is assessed periodically; the device is then further adjusted and the therapy program updated as needed to achieve the pre-defined goals. The device is intended to be worn only during the time scheduled by the practitioner (e.g., 30 minutes a day).

Intended Use / Indications for Use

The AposTherapy System is intended to be used by trained professionals for adjusting the distribution of weight/force(s) that is being applied to a lower limb. The AposTherapy System is intended for patients with knee osteoarthritis, to help temporarily reduce knee pain and improve lower extremity function during activities of daily living.

Summary of Technological Characteristics

The intended use of the device is consistent with the classification regulation for a limb orthosis, which defines a class I, 510(k)-exempt device. The adjunctive indication for knee pain due to osteoarthritis does not represent a separate intended therapeutic effect or raise different questions of safety or effectiveness as compared to legally marketed devices of this type, because pain reduction is an outcome of the intended use to re-align limbs and improve their function.

The fundamental technological characteristics of the AposTherapy System are consistent with the classification regulation for a limb orthosis. As defined in 21 C.F.R. § 890.3475, the subject device is worn on the lower extremities, and is used to align body structures for functional improvement. Corrective shoes are specifically listed in the regulation as examples of this type of device.

Moreover, the AposTherapy System's underlying technological principle/mechanism of action is shared with other legally marketed devices. Specifically, Apos Therapy achieves the intended clinical purpose through two mechanisms: 1) adjusting the foot's points of contact with the ground to affect the distribution of weight/force(s) applied to the lower limb, and 2) instability during gait exercise. As noted above, the subject device is in the form of an orthosis shoe, consistent with devices cleared under 21 C.F.R. § 890.3475. The AposTherapy System, like other corrective shoes, is calibrated to the individual patient's needs and adjusted as the patient progresses, and with clinician's assessment of load bearing, gait, and related indicators of function and/or pain at baseline and throughout the course of treatment.

Performance Data

The AposTherapy System underwent non-clinical testing conducted to ensure that the device can perform as intended. In all instances, the AposTherapy System functioned as intended and each test's success criteria were met.

In addition, clinical testing was performed to demonstrate the device's safety and effectiveness for the proposed indications. A prospective, randomized, sham-controlled clinical trial that enrolled 220 knee OA patients was completed. The data from this study is the primary evidence to support device clearance. The results of the study demonstrate that the AposTherapy System temporarily improves lower extremity function during activities of daily living and reduces knee pain due to OA in the intended treatment population. Specifically, WOMAC global scores at week 24 were 1.37±1.15 and 2.47±1.80 in the AposTherapy and sham arms, respectively (1.10 mean difference, Cohen's d of 0.73). In addition, 83% of the AposTherapy arm (95% CI: 74% - 89%) and 42% of the sham arm (95% CI: 33% - 52%) achieved 50% change in WOMAC pain score at week 24 (adjusted odds

ratio: 6.67 (95% CI: 3.54-12.58) and adjusted Mantel-Haenszel risk difference of 0.42 (95% CI: 0.28 – 0.52)).

Additional clinical evidence from the published literature and other independent studies investigating the device's performance for knee pain and function outcomes have been completed and are supplemental evidence in support of device clearance. These supplemental sources also show that the AposTherapy System has been thoroughly investigated and has achieved consistent improvement on knee pain and function outcomes. Consequently, the totality of the data strongly supports clearance of the device for use in patients with knee OA to temporarily improve knee pain and lower extremity function during activities of daily living.

Conclusions

The AposTherapy System fits within the definition set forth in the classification regulation for a limb orthosis device. Moreover, the AposTherapy System has the same intended use and similar indications for use, technological characteristics, and principles of operation as other legally marketed limb orthoses. Finally, bench and clinical data demonstrate that the AposTherapy System is as safe and effective as other legally marketed lower limb orthoses. Thus, the AposTherapy System is substantially equivalent.