



December 23, 2019

Viasonix Ltd.
Dan Manor
CEO
10 Hamelacha Street
Raananna, IL 4366105

Re: K192607
Trade/Device Name: LiteWalk
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: September 16, 2019
Received: September 20, 2019

Dear Dan Manor:

This letter corrects our substantially equivalent letter of December 19, 2019.

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather L. Dean -S

for: Vivek Pinto, Ph.D.

Director

DHT5B: Division of Neuromodulation
and Physical Medicine Devices

OHT5: Office of Neurological
and Physical Medicine Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K192607

Device Name

LiteWalk

Indications for Use (Describe)

The LiteWalk is intended for home and hospital use for temporary increase in local blood circulation in the lower extremities and temporary relief of minor muscle aches and pains where applied .

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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SECTION 5 – 510(K) SUMMARY

5.1 ADMINISTRATIVE INFORMATION

Date:	10-September-2019
Submitter:	Viasonix Ltd. 10 Hamelacha Street Raanana , ISRAEL 4366105 Phone : 972-9-7441692
Official Correspondent:	Dan Manor, CEO
Trade Name:	LiteWalk
Classification Name:	Powered inflatable tube massager
Classification Number:	21 CFR 890.5650
Product Code:	IRP
Device Class:	Class II
Predicate Devices:	PPCID, K000655

5.2 DEVICE DESCRIPTION

The LiteWalk is a pneumatic sequential foot compression device, designed primarily for temporary improvement in blood flow circulation in the lower limb. The system is based on a pneumatic unit that includes a pump, valves, pressure sensor and tubing, and is fed by an external power supply of 12V DC.

The unit is connected through 2 sets of 4-tubes to 2 inflatable sandals. Each sandal has 4 inflatable pressure chambers, located to match the foot anatomy: heel, arch, metatarsals, and toes. The sandals come in a pair, for right and left feet, and in 3 sizes: small, medium, large. The operation is based on sequential inflation/deflation of the 4 chambers, from heel to toes.

5.3 INTENDED USE AND INDICATIONS FOR USE

The LiteWalk is Intended for home and hospital use for temporary increase in local blood circulation in the lower extremities and temporary relief of minor muscle aches and pains where applied

5.4 CONTRAINDICATIONS

The LiteWalk is not intended for use if any of the following medical conditions exist. Consult with a physician whenever there is doubt whether it is clinically safe to use the LiteWalk.

- Presumptive evidence of congestive heart failure where increase in blood returned to the heart could be detrimental
- Pre-existing deep vein thrombosis (DVT) or blood clots
- Existing hemorrhagic disease or coagulation problems
- Thrombophlebitis
- Pulmonary embolism

5.5 SUMMARY OF TECHNICAL CHARACTERISTICS

The LiteWalk device is similar to the predicate device cited above [section 5.1] intended for powered inflatable tube massager applications.

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, the intended use, use environment and target patient population of the LiteWalk device is substantially equivalent to the predicate device cited above.

5.5.1 Summary table of Comparison

Specification	LiteWalk	PPCID	Differences discussion
510(k) number	Proposed Device	K000655	NA
Manufacturer	VIASONIX LTD.	Medical Dynamics LLC	NA
Product Regulation	21CFR890.5650 - Powered inflatable tube massager	21CFR890.5650 - Powered inflatable tube massager	Identical
Product Code	IRP - Powered inflatable tube massager	IRP - Powered inflatable tube massager	Identical
Indications for use	Intended for home and hospital use for temporary increase in local blood circulation in the lower extremities and temporary relief of minor muscle aches and pains where applied	Intended for home and hospital use for temporary increase in local blood circulation in the lower extremities and temporary relief of minor muscle aches and pains where applied	Identical
Contraindications	Use of the LiteWalk is contraindicated in patients for whom: <ul style="list-style-type: none"> • Presumptive evidence of congestive heart failure where increase in blood returned to the heart could be detrimental • Pre-existing deep vein thrombosis (DVT) or blood clots • Existing hemorrhagic disease or coagulation problems • Thrombophlebitis • Pulmonary embolism 	Use of the PPCID is contraindicated in patients for whom an increase in blood returned to the heart could be detrimental, including those with presumptive evidence of congestive heart failure, pre-existing deep vein thrombosis, thrombophelbitis, existing hemorrhagic disease, coagulation problems, or pulmonary embolism	Identical
Environment of Use	Hospital and Home care	Hospital and Home care	Identical
Rx OR OTC	OTC	OTC	Identical
Mode of compression	Sequential	Sequential *Not publicly available	Similar to the predicate
Use Time [min]	Recommended 30 min	30 min or more *Not publicly available	Similar to the predicate
Sequential cycles time	2-3 cycles per minute	2-3 cycles per minute *Not publicly available	Similar to the predicate
Modes	1 mode : Sequential inflation/deflation of 4 chambers from heel to toes	1 mode : Sequential inflation/deflation of 4 chambers from heel to toes *Not publicly available	Similar to the predicate

Specification	LiteWalk	PPCID	Differences discussion
Max Pressure	160 mmHg	80-200 mmHg *Not publicly available	Similar to the predicate. Within the predicate pressure range
Types of Garments	Foot Sandal	Foot Sandal *Not publicly available	Similar to the predicate. Foot Sandal type is supported by the predicate device
Garment sizes	3 sizes: small, medium, large	3 sizes: small, medium, large *Not publicly available	Similar to the predicate
Patient contact materials	Polyester [PVB0123, Colored Fabric]	Not known *Not publicly available	Similar to the predicate. Both sharing a fabric for the Sandals. LiteWalk Polyester skin contact material comply with ISO 10993
Patient contact	Non conductive	Non conductive *Not publicly available	Similar to the predicate
Number of chambers	4	4 *Not publicly available	Similar to the predicate
Line Voltage / Frequency	100-240 Vac / 50-60Hz 12V , 2.0A	115 Vac / 60 Hz, 7W *Not publicly available	Similar to the predicate
Power Consumption	8 W	7W *Not publicly available	Similar to the predicate
Safety feature	Power button on main unit allows user to stop therapy session at any time.	Power button on main unit allows user to stop therapy session at any time. *Not publicly available	Similar to the predicate
User Interface	No	No *Not publicly available	Similar to the predicate
Indicator	Green led	Led *Not publicly available	Similar to the predicate
Technology	Compressor and valve system which sequentially inflates inflatable chambers	Compressor and air distributor system which sequentially inflates inflatable chambers *Not publicly available	Both sharing the same functionality. The valve allows better control over inflation and allows quick deflation. This slight change doesn't impact product safety and performance.
Standards	IEC 60601-1 IEC60601-1-2 IEC60601-1-11 ISO 10993-1	IEC 60601-1 IEC60601-1-2 ISO 10993-1 *Not publicly available	Similar to the predicate. The LiteWalk meets all latest standards edition

5.6 UTILIZATION OF STANDARDS AND GUIDANCE'S:

The LiteWalk meets the following standards:

1. IEC 60601-1:2005+A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3. IEC 60601-1-11: 2015 - Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
4. IEC 62366-1: 2015 - Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
5. IEC 60601-1-6: 2013 [Edition 3.1] - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

5.7 SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Summary of Non-Clinical Tests:

The LiteWalk device have been thoroughly tested through verification of specifications and validation, including software validation.

5.8 SUMMARY OF CLINICAL PERFORMANCE DATA

No clinical study was conducted to support this application.

5.9 CONCLUSIONS

Based on its underlying technology and bench tests performed, the LiteWalk is substantially equivalent to the predicate device.