January 22, 2024

JPS Corporation
℅ Kelli Anderson
President & Owner
Tech2Med, LLC
6450 Old Darby Trl NE
Ada, Michigan 49301

Re: K230841
Trade/Device Name: NailLift
Regulatory Class: Unclassified
Product Code: MQZ
Dated: March 27, 2023
Received: March 28, 2023

Dear Kelli Anderson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices

Office of Product Evaluation and Quality

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230841

Device Name
NailLift

Indications for Use *(Describe)*
NailLift is an ingrown toenail corrector that corrects nail curvature by lifting the curved toenails into a more natural shape upon application. The correction of nail curvature results in decreased pain.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY – K230841

(a)(1). Submitted By: JPS Corporation
Toho Edogawabashi Bldg. 3F
1-24-8 Sekiguchi, Bunkyo-ku Tokyo
112-0014 Japan
Mail: info@jps.ac

Contact Person: Kelli Anderson
Principle Regulatory Consultant
Office: (574) 527-9214

Date: January 17, 2024

(a)(2). Proprietary Name: NailLift

Common Name(s): Prosthesis, Nail

Classification Name: Unclassified

Regulatory Class: Unclassified
Product Codes: MQZ

(a)(3). Predicate Device: K162525 – Oniko Nail Brace, Begum Saglik, Tibbi Malzemeler & Danismanlik Ltd Sti

(a)(4). Device Description

The NailLift is a device for correcting the shape for painful and/or deformed nails without surgery.

(a)(5). Indications for Use

NailLift is an ingrown toenail corrector that corrects nail curvature by lifting the curved toenails into a more natural shape upon application. The correction of nail curvature results in decreased pain.

(a)(6). Technological Characterizes

The NailLift device utilizes Nitinol alloy wires to lift the outer edges of the ingrown or deformed nail. The device uses steel clips to attach the wire form to the nail.

(b)(1). Substantial Equivalence: - Non-Clinical Evidence Performance Data

Performance evaluation of the NailLift device demonstrated that the device functions in a similar manner to the predicate. Cytotoxicity, sensitization and irritation testing completed per ISO 10993 show the materials used do not illicit a biological response.

(b)(2). Substantial Equivalence: - Clinical Evidence

Clinical feedback supporting pain relief when utilizing the NailLift device was collected from 149 patients utilizing a Visual Analogue Scale (VAS). Patients were asked how much pain they have on a scale of 0 to 10, with 0 meaning no pain and 10 meaning the worst pain possible. Patient's were

asked for pain feedback at the various intervals provided in the table below. Feedback showed 99% of patients experienced pain relief upon NailLift application.

	Question	Difference of pain*											
		-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	0	<1
1	Before coming into the clinic VS Immediately after NailLift application.	0	0	2	11	35	24	44	27	4	0	2	0
2	Immediately after NailLift application VS After NailLift removal	0	0	0	0	2	2	1	3	3	7	128	0
3	Before coming to the clinic VS After NailLift removal	0	1	6	10	43	23	38	25	3	0	0	0

The difference of pain is the difference of the scale of pain the patients answered between the times. Eg.) The scale of pain was 8 before coming to the clinical and 6 immediately after NailLift application, yielding a -2 as the difference of pain.

(b)(3). Substantial Equivalence – Conclusions

The NailLift device is substantially equivalent to the Oniko Nail Brace (K162525). The NailLift device has the same intended use and principles of operation as the predicate device. The minor differences between the NailLift device and the Oniko Nail Brace do not raise different questions of safety and effectiveness.