DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 25, 2018

Begum Saglik Hizmetleri Tibbi Malzemeler Danismanlik Lsti
Fatma Erdogan
Official Correspondent
Sanatkarlar Cad. No:5 Angora Evleri
Beysukent Cayyolu, 06800 TR

Re: K162525
Trade/Device Name: Oniko nail brace
Regulatory Class: Unclassified
Product Code: MQZ
Dated: March 5, 2018
Received: March 5, 2018

Dear Fatma Erdogan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K162525

Device Name
Oniko nail brace

Indications for Use *(Describe)*
To correct the shape of overcurved and/or painful nails without operation. To loosen and to give shape to thickened nails, overcurved nails and pincer nails without operation.

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

Applicant: Begum Saglik, Tıbbi Malzemeler & Danısmanlık Ltd Sti
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Contact person: Fatma Gülru Erdogan
gulruer@gmail.com

Date Summary Prepared: April 17, 2018
510(k) Number: K162525

Trade Name: Oniko nail brace
Name of device: Nail brace

Classification: Unclassified
Product code: MQZ
Device Contact Class: Permanent (>30 days)
Advisory Panel: General & Plastic Surgery

Predicate Device: K960843- Stop-n-grow, European Touch Co., Inc.

Device Description: Oniko nail brace is a device for correcting the shape for painful and /or overcurved nails without the use of any operation or anesthesia.

Intended Use: To correct the shape of overcurved and/or painful nails without operation. To loosen and give shape to thickened nails, overcurved nails and pincer nails without operation.

Technological Characteristics: Oniko nail brace is composed of metal hooks and silicone bands. The metal hooks grasp the nail sides open to correct the shape or painful and/or overcurved nails.

Performance Data: Assessment of the Oniko nail brace demonstrated that the device is non-cytotoxic non-sensitizer, and non-irritant, which are supported with clinical results.

Substantial Equivalence Discussion/Conclusion: Oniko nail brace is substantially equivalent to the Stop-n-grow (K960843). Oniko nail brace does not raise different questions of safety and effectiveness compared to the predicate device. The Oniko Nail Brace has similar intended use and principles of operation as the predicate device. The minor differences between Oniko nail brace and Stop-n-grow do not raise different questions of safety and effectiveness.