



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

TMJ Services, LLC
% Dawn Norman
Executive Vice President
MRC-X, LLC
6075 Poplar Ave; Suite 500
Memphis, Tennessee 38119

September 25, 2017

Re: K170985
Trade/Device Name: Urbanek Device
Regulatory Class: Unclassified
Product Code: MQC
Dated: August 24, 2017
Received: August 25, 2017

Dear Ms. Dawn Norman:

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 (DICE) 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 (DICE) 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,


Mary S. Runner -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K170985

Device Name

Urbanek Device

Indications for Use (Describe)

The Urbanek Device is for the amelioration of clenching and bruxing associated with TMD and is to be used to aid in the relief of symptoms of TMD/TMJ.

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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K170985
510(k) Summary

Proprietary Name Urbaneck Device

Date of Submission: September 25, 2017

Company: TMJ Services
 ATTN: Anthony P. Urbaneck, DDS, MD, MS
 2009 Mallory Ln
 Franklin, TN 37067
 Phone: 615-771-2189

Establishment

Registration: N/A

Primary Contact: Dawn Norman, MS
 Exec. Vice President MRC-X, LLC
 6075 Poplar Avenue, Suite 500
 Memphis, TN, 38119
 Phone: 618-604-3064

Company/Secondary

Contact: TMJ Services
 Anthony P. Urbaneck, DDS, MD, MS
 2009 Mallory Ln
 Franklin, TN 37067
 Phone: 615-771-2189

Trade Name: Urbaneck Device

Common Name: Mouthguard, Prescription

Classification: Unclassified

Product Code: MQC, OCO

Regulation Number: Pre-amendment

Panel: Dental

Predicate Devices:

Primary Predicate Device:

- NTI-TSS Inc.: NTI Tension Suppression System – K010876 (Cleared 06/20/2001)

Reference Predicate Device:

- MigraTherapy, LLC Brux: TMD QuickSplint– K111066 (Cleared 11/22/2011)

Device Description: The Urbanek Device is an intraoral, maxillary posterior dis-occluding device designed to aid in the treatment of clenching and bruxing associated with TMD/TMJ. The purpose of the device is to keep posterior maxillary and mandibular teeth (molars and premolars) from occluding in the centric or eccentric positions. Constructed of heat cured dental resin and two metal ball clasps for retention, the device is customized for each patient (per prescription by a dentist).

The device is designed to be worn for 24 hours per day (except at meals), 7 days per week for a set interval of time (e.g., 9 weeks). At scheduled follow-up visits, patients are assessed for symptom relief and the device inspected for comfort, proper design, excessive wear and vertical dimension for the inter-incisal distance with the device in place. The device may be adjusted for comfort and inter-incisal distance to ensure no posterior tooth or portion of a tooth occludes with the opposing tooth.

This device is effective because it allows the posterior teeth to be separated (disoccluded) for a period of time in the centric relation position. Disocclusion helps to relieve TMJ/TMD symptoms by stabilizing jaw muscles and joints. By stabilizing jaw muscles and joints to prevent overuse, inflammation of tissue within the temporomandibular joint resolves and healing is allowed to occur.

Indications for Use: The Urbanek Device is for the amelioration of clenching and bruxing associated with TMD and is to be used to aid in the relief of symptoms of TMD/TMJ.

Comparison of Subject and Predicate Intraoral Devices

Device	Urbanek Device (Subject Device)	NTI-TSS NTI Tension Suppression System (K010876); Primary Predicate	MigraTherapy LLC Brux- TMD QuickSplint (K111066); Reference
Product Code	OCO, MQC	OCO	MQC
Indications for Use	The Urbanek Device is for the amelioration of clenching and bruxing associated with TMD and is to be used to aid in the relief of symptoms of TMD/TMJ.	<p>Treatment of tooth wear from bruxing and clenching</p> <p>Treatment of muscle pain associated with muscle dysfunction</p> <p>Diagnostic treatment planning</p> <p>The NTI-tss protocol is indicated for the prevention of medically diagnosed migraine pain and jaw disorders through the reduction of trigeminally innervated muscular activity</p>	<p>1. Protection of teeth and restorations from injury due to bruxism or clenching.</p> <p>2. Temporary relief of Temporomandibular Joint Disorder (TMD) and bruxism by reducing muscle tension.</p> <p>3. Temporary treatment of Temporomandibular Disorder (TMD) along with the relief of associated headaches and pains.</p> <p>The intended user includes patients diagnosed with bruxism, patients with headaches and pain related to bruxism, Patients with TMD, patients with headaches and pain related to TMD and patients who may damage teeth or dental restorations from the clenching and grinding related to bruxism activity.</p>
Material	<ul style="list-style-type: none"> Thermoplastic resin ASTM 313 Stainless Steel 	<ul style="list-style-type: none"> Thermoplastic resins 	<ul style="list-style-type: none"> Polycarbonate tray vinyl polysiloxane liner
Mechanism of action	Disocclusion	Disocclusion	Disocclusion
Removable?	Yes	Yes	Yes
Device placement	Palate and anterior maxillary arch	Anterior maxillary or mandibular arch	Anterior maxillary or mandibular arch
Location of disocclusion	Upper molars and premolars	Lower incisors	Upper/lower incisors from bicuspid to bicuspid

Technological

Characteristics:

The material base for the Urbanek Device is FDA cleared and previously demonstrated to be safe for dental use. The Urbanek Device is substantially equivalent to the predicate and reference devices as its primary mode of action, like that of the predicate and reference devices, is to keep the posterior maxillary and mandibular teeth (molars and premolars) from occluding in the centric or eccentric positions. This disocclusion results in the alleviation of pressure on the temporomandibular joints. The primary difference between the proposed device and the predicate(s) is where the device sits within the oral cavity. The Urbanek Device sits on the palate of the mouth while the NTI-TSS NTI Tension Suppression System uses the lower incisors and the Brux TMD QuickSplint is an anterior bite plate that covers either the upper or lower front teeth from bicuspid to bicuspid. Although, the positions of the device within the oral cavity are different, the intent in all of the devices is disocclusion. The proposed and predicate devices are all patient specific and reusable for the given patient.

Performance Testing:

Performance testing has not been performed as there are no recognized standards to which prescription mouthguards are tested; however, the material composition of the Urbanek Device base has been found in legally marketed devices and found previously safe for dental use since 2001 and meets the requirements of ISO 20795-1 :2008 Dentistry -- Base polymers -- Part I: Denture base polymers (previously ISO 1567:1999).

Conclusion:

The subject Urbanek Device has similar indications for use, mode of action, technological characteristics and materials as the predicate devices. The minor differences between the Urbanek device and the predicate devices raise no new questions of safety and effectiveness. Thus, the Urbanek Device is substantially equivalent to the predicate devices.