510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the DEVICE is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) Summary.

Applicant:	MigraTherapy LLC.
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Contact Person:	Louis Kirby, MD
Telephone:	602 908-1680 or 760 840-6034
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Preparation Date:	29 March 2011
Device Trade Name:	Brux-TMD QuickSplint
Common Name:	None
Classification Name:	Unclassified
Product Code:	MQC
Legally Marketed Predicates:	1. MCI Clenching Inhibitor 2. Custom fabricated full occlusal coverage 3. Dr. Hays Bite Guard

510(k) Summary of Safety and Effectiveness for the Brux-TMD QuickSplint device, continued:

Device Description: The Brux-TMD QuickSplint is a patented anterior bite plate that covers the upper or lower front teeth from bicuspid though bicuspid. It is a two-component device with a hard plastic shell and a softer compliant lining that conforms to the supporting teeth. The operator may optionally place it on the anterior maxillary or mandibular arch.

The Brux-TMD QuickSplint is easily and quickly assembled in a provider's office for same day use by the patient.

While it is worn, the Brux-TMD QuickSplint temporarily inhibits the full force of parafunctional teeth clenching, and gives the pericranial musculature an opportunity to relax. This reduces the muscular tension that underlies the pain associated with many bruxism headaches and the pain associated with TMD dysfunction. It reduces the muscle tension in trigeminal innervated cranial-facial muscles, thereby reducing the pain occurrence. In addition, it physically protects the teeth from nighttime bruxing activities by covering the dental occlusal surfaces with a durable plastic covering.

Intended Use:

1. Protection of teeth and restorations from injury due to bruxism or clenching.
2. Temporary relief of Temporo Mandibular joint Disorder (TMD) and bruxism by reducing muscle tension.
3. Temporary treatment of Temporal Mandibular Disorder (TMD) along with the relief of associated headaches and pains.

The Brux-TMD QuickSplint is to be worn at night and removed in the morning except in the presence of severe pain in which case it may be worn during the day for limited periods as instructed by the prescriber.

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.

In the professional office, Brux-TMD QuickSplint can be placed the same day as the office visit and following dental procedures (endodontic, oral surgery, placement of cosmetic dental prosthetics and periodontal surgery) where bruxing activity might damage the results or cause increased pain. The Brux-TMD QuickSplint is described as temporary and should be considered transitional if the

patient experiences benefits.

These indications and patient populations are substantially the same as the predicate devices.

Comparison of predicate devices

	Brux-TMD QuickSplint K11066	MCI-Myohealth Clenching inhibitor K040315	Full coverage, custom fabricated bite plate (pre-1972 device)	Dr. Hays Bite Guard K014079
Indications	Protection of teeth and restorations from injury due to bruxism or clenching	Same	Same	Same
	Treatment of Temporal Mandibular Disorder (TMD) along with the relief of associated headaches and pains.	Same	Same	Same
	Relief of bruxism related headaches and pains.	Same	Same	Same
Regulatory	Pre-Market Notification 510(k)	Pre-Market Notification 510(k)	Preamendment	Pre-Market Notification 510(k)
Design	Custom fitted mouth guard	Same	Same	Same
Use	Nighttime	Same	Same	Same
Reusable	Yes	Same	Same	Same
Method of disinfection	Soap and water; air dry	Same	Same	Same
Materials	Polycarbonate tray; vinyl polysiloxane liner	Polycarbonate, thermoplastic liner	methacrylate acrylic	Lexan and Elvax
Risk of exposure	None	None	None	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NOV 22 2011

Dr. Louis Kirby
CEO
Migra Therapy LLC
4403 Manchester Avenue, Suite 103
Encinitas, California 92024

Re: K111066
Trade/Device Name: Brux-TMD QuickSplint
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MQC
Dated: November 10, 2011
Received: November 14, 2011

Dear Dr. Kirby:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Intended Use:

Indications

1. Protection of teeth and restorations from injury due to bruxism or clenching.
2. Relief of bruxism related headaches and pains.
3. Treatment of Temporal Mandibular Disorder (TMD) along with the relief of associated headaches and pains.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Susan Runner 11/17/11

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K111066