



Food and Drug Administration  
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December 10, 2015

12<sup>th</sup> Man Technologies, Inc.  
Mr. Alex Stenzler  
President  
7245 Garden Grove Blvd., Suite C  
Garden Grove, California 92841

Re: K151933

Trade/Device Name: BRX PRO™  
Regulation Number: Unclassified  
Regulation Name: Unclassified  
Regulatory Class: Unclassified  
Product Code: MQC  
Dated: October 28, 2015  
Received: October 30, 2015

Dear Mr. Stenzler:

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" (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 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 yours,

 Tina  
Kiang -S

for Erin I. Keith, M.S.

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 Statement**

**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K151933  
Device Name: BRX PRO™

**Indications for Use:**

The BRX PRO™ Bruxism Guard is indicated to protect the teeth and reduce damage caused by bruxing or nighttime grinding and reducing the noise associated with bruxing and grinding.

Prescription Use  X  AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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## 510(k) Summary

Submitter's Name	12 <sup>th</sup> Man Technologies, Inc. 7245 Garden Grove Blvd., Suite G Garden Grove, CA 92841 1.714.705.4576
Registration Number	3009108174
Contact Name	Alex Stenzler 12th Man Technologies, Inc. 7245 Garden Grove Blvd., Suite G Garden Grove, CA 92841 Telephone: 1.714.705.4576 Fax: 1.714.373.0505 Email: alex.stenzler@12thmantec.com
Date Prepared	December 10, 2015
Device Trade Name	BRX PRO™
Device Common Name	Bruxism guard
Classification Name	None
Product Code	MQC
Device Classification	Unclassified
Panel	Dental
510(k) Submission	Traditional
Legally Marketed Equivalent	SmartGuard (K123161) Brux-TMD QuickSplint (K111066)

**Description**

The BRX PRO is a prescription dual arch bruxism guard which protects the teeth and reduces the damage caused by nighttime bruxism and reduces the noise of bruxing or nighttime grinding. The BRX PRO's two arch trays, when filled with impression material, cover approximately eight teeth on each of the upper and lower arches, thereby creating an air-gap between the posterior teeth that prevents tooth contact upon clenching. The two polycarbonate trays are connected in the front with a dual position stainless steel "T-bar" pin in the upper tray and a pair of stainless steel slots in the lower tray that can be set by the prescriber to maintain the BRX PRO trays in a neutral position by selecting one of four positions, while allowing for lateral mandibular movement.

The impression materials that can be used to interface with the teeth are any of the approved for sale materials such as Mousse PVS (Parkell), individually selected by the dentist or physician fitting the patient with the BRX PRO and are typically a polyvinyl siloxane (PVS) available from many dental supply sources.

### **Predicate Devices**

The design of the BRX PRO is substantially equivalent to the SmartGuard (K123161) and the Brux-TMD QuickSplint (K111066). The predicate devices are mouth guards designed to protect the teeth and reduce damage caused by bruxing or nighttime grinding and reduce the noise associated with bruxing and grinding. The Brux-TMD QuickSplint uses thermoplastic arches filled with impression material to interface to the teeth. The impression material is the same PVS as recommended for use in the BRX PRO and can be fitted in a prescriber's office. The BRX PRO Instructions-for-Use recommends that the dentist or prescriber uses commercially available polyvinyl siloxane impression materials to create the tray liner to obtain the ideal fit. Because these mouth guards can be used on either the upper or lower teeth, some dentists prescribe that the patient use mouth guards on both arches. The SmartGuard, Brux-TMD QuickSplint and the BRX PRO all use partial arches to create a posterior arch air gap.

### **Description of Operation**

The BRX PRO comes with two sets of trays. A pair of impression trays (upper and lower) are sequentially filled with a PVS impression material by the prescriber to fit to the patient. Once trimmed by the dentist, the impressions are transferred to the treatment trays. The upper tray has a "T-bar" pin that extends out from the bottom of the tray. The pin has an anterior or posterior orientation so that when combined with the two slots in the lower tray, provides for a selection of four positions to fit the patient who may have a natural bite ranging from a Class I to Class III as well as an edge-to-edge bite position. The "T-bar" pin is inserted into the slot and rotated 90 degrees to connect the two trays. The slots provide for lateral movement of the mandible.

### **Indications for Use:**

To protect the teeth and reduce damage caused by bruxing or nighttime grinding and reducing the noise associated with bruxing and grinding.

**Substantial Equivalency Summary Comparison Table**

<b>Element of Comparison</b>	<b>BRX PRO™</b>	<b>SmartGuard</b>	<b>Brux-TMD QuickSplint</b>
<b>Indications for Use</b>	To protect the teeth and reduce damage caused by bruxing or nighttime grinding and reducing the noise associated with bruxing and grinding.	To reduce damage to the teeth and reduce noise associated with bruxing and/or grinding	Prevent teeth grinding, reduces jaw clenching and damage to teeth
<b>Regulatory</b>	Pre-Market Notification 510(k)	K123161	K111066
<b>Environment of Use</b>	Home Setting	Home Setting	Home Setting
<b>Design</b>	Custom fitted mouth guard	Custom fitted mouth guard	Custom fitted mouth guard
<b>Use</b>	Night time	Night time	Night time
<b>Daily Duration of Use</b>	Up to 8 hours per night for up to 30 days	Up to 12 hours per 24 hour period	While asleep and limited daytime use
<b>Transitional Device</b>	Yes	NA	Yes
<b>Reusable</b>	Yes, Single Patient	Yes, Single Patient	Yes, Single Patient
<b>Sterile</b>	No	No	No
<b>Method of disinfection</b>	Denture cleaner	Denture cleaner	Soap and water
<b>Tray Materials</b>	Polycarbonate and stainless steel	Elvax (ethylene vinyl acetate copolymer)	Polycarbonate
<b>Tray manufacturing method</b>	Injection molded	Injection molded	Injection molded
<b>Impression Material</b>	Prescriber selected and supplied PVS	Elvax (ethylene vinyl acetate copolymer)	Prescriber selected and supplied PVS

## Non-Clinical Testing

Non-clinical test results are submitted to confirm product conformance with device requirements and substantial equivalence to predicate device. These bench tests included:

1. Packaging and Assembly / Shipping
2. Materials Specifications
3. Labeling Verification
4. Physical Characteristics

Physical Parameter	Test Method	ISO 20795-1:2013 Requirement	Pass/Fail
Flexural Modulus	ISO 178	$\geq 2000$ MPa	Pass
Flexural Stress	ISO 178	$\geq 65$ MPa	Pass
Water Absorption	ISO 62	$\leq 32$ $\mu\text{g}/\text{m}^3$	Pass
Water Solubility	ISO 62	$\leq 1.6$ $\mu\text{g}/\text{m}^3$	Pass
Charpy Notched Impact Strength (Linear relation with Fracture)	ISO 179	$\geq 0.9$ KJ/m <sup>2</sup>	Pass

5. Manufacturing

### Applicable Standards Met

Standard or Regulation	Standard Organization or Regulatory Body	Name of Test Performed	Test Results
ISO 10993-1:2009 COR 1 2010	International Standards Office	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process	Pass
ISO 10993-5:2009	International Standards Office	Biological Evaluation of Medical Devices – Part 5 Tests for in vitro cytotoxicity	Pass
ISO 10993-10:2009	International Standards Office	Biological Evaluation of Medical Devices – Part 10 Tests for irritation and skin sensitization	Pass
BS EN ISO 15223-1:2012	International Standards Office	Medical Devices – Symbols to be used with Medical Devices Labels, Labelling and Information to be supplied– Part 1: General Requirements	Pass
BS EN ISO 20795-1:2013	International Standards Office	Dentistry – Base polymers, Part 1: Denture base polymers	Pass

**Substantial Equivalence**

Based on the design, intended use, principle of operation, technological characteristics, performance data, and attribute comparison above, the 12th Man Technologies, Inc. BRX PRO bruxism guard is substantially equivalent to the currently marketed predicate devices which have been previously reviewed for market clearance by the FDA.

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*[510(k)] Number*