Dear Cheryl Fisher:

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. 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 located 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.
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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For 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)
Not Known

Device Name
Kava and Kava with Herbst device(s)

Indications for Use (Describe)
The Kava and Kava with Herbst device(s) are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

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)

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

Kava and Kava with Herbst device(s)

1. Submission Sponsor

Sketchpad Innovations LLC
10767 Glendover Ln.
San Diego
CA, 92016
United States
Contact: Phillip “Sonnie” Bocala
Title: CEO

2. Submission Correspondent

FisherMed Consulting, LLC
820 Civic Center Drive
Santa Clara, CA 95050
Office Phone: (408) 410-5920
Contact: Cheryl Fisher
Title: Principal Consultant, RA/QA

3. Date Prepared

9/19/2018

4. Device Identification

Trade/Proprietary Name: Kava and Kava with Herbst
Common/Usual Name: Intraoral Devices for Snoring and /or Obstructive Sleep Apnea
Classification Name: Intraoral Devices for Snoring and /or Obstructive Sleep Apnea
Regulation Number: 872.5570
Product Code: LRK, Device, Anti Snoring- Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.
5. Legally Marketed Predicate Device(s)

Primary Predicate
K153291 OptiSleep Device by SICAT

Reference Device
K113516 CAST device by TheraSom

6. Indication for Use Statement

The Kava and Kava with Herbst device(s) are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

7. Device Description

The Kava and Kava with Herbst are simple hardware devices. They are oral appliances and will be manufactured by a dental laboratory to and on the order of a dentist, physician or licensed practitioner. Each appliance is customized for patients.

The Kava and Kava with Herbst are intra-oral devices used for treating snoring and mild to moderate Obstructive Sleep Apnea (OSA). They consists of two custom fitted trays which fit over the upper and lower dentition of a patient and engage by means of adjustable metal screws or lugs. The devices function as mandibular repositioners, which act to increase the patient’s pharyngeal space by reducing obstructions of the airway during sleep and improve their ability to exchange air.

The devices are retained on the teeth by labial and lingual positioned ball clasps, typically located in the undercuts of each splint.

The devices are custom made for each patient and have an adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device.
8. **Substantial Equivalence Discussion**

The following table compares the Kava and Kava with Herbst device(s) to the predicate device(s) with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

**Table 5A – Comparison of Characteristics**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Kava and Kava with Herbst</th>
<th>Primary Predicate SICAT OPTISLEEP</th>
<th>Reference Device TheraSom-CAST</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>510 (k) Number</td>
<td>Not Known</td>
<td>K153291</td>
<td>K113516</td>
<td>Same method</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Sketchpad Innovations LLC</td>
<td>SICAT GmbH &amp; Co</td>
<td>Family Dental Service PC</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Primary Device Similarities to support Substantial Equivalence**

<table>
<thead>
<tr>
<th>Classification #</th>
<th>872-5570</th>
<th>872-5570</th>
<th>872-5570</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Code</td>
<td>Primary LRK</td>
<td>Primary LRK</td>
<td>Primary LRK</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Secondary LQZ</td>
<td>Secondary LQZ</td>
<td>Secondary LQZ</td>
<td></td>
</tr>
<tr>
<td>Indications for use</td>
<td>The Kava and Kava with Herbst device(s) are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.</td>
<td>In adult population • To reduce or alleviate snoring • To reduce or alleviate mild to moderate obstructive sleep apnea (OSA)</td>
<td>The TheraSom-CAST is used to reduce or alleviate the occurrence of snoring and/or for the treatment of mild to moderate obstructive sleep apnea (OSA) in patients</td>
<td>Same</td>
</tr>
<tr>
<td>Mode of Action</td>
<td>These devices function as a mandibular repositioner, which acts to increase the patient's pharyngeal space, by reducing obstructions of the airway and improving their ability to exchange air during sleep.</td>
<td>This device functions as a mandibular repositioner, maintaining the lower jaw in a forward position during sleep. This mechanical protrusion acts to increase the patient's pharyngeal space, improving the ability to exchange air during sleep by reducing mechanical obstructions of the airway.</td>
<td>The device functions as a mandibular repositioner, which acts to improve the patient's ability to breathe without obstruction of the pharyngeal airway.</td>
<td>Similar mode of action with slight technical deviations discussed below, not incurring additional patient risks.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>
| Material | Acrylic  
*The main parts of the device(s) are made of Acrylic Material, Stainless Steel, and Dental Alloy Material* | Milled Acrylic  
*The main parts of the device are made of Polymethylmethacrylate. The exchangeable connectors are made of Polyamide* | Cast Metal  
Dental Alloy Material | The Kava and Kava with Herbst and OptiSleep devices are made of an acrylic material while the TheraSom is made of a dental metal alloy there is no significant difference between the Kava and Kava with Herbst and the OptiSleep |
<table>
<thead>
<tr>
<th>Mode of Care</th>
<th>Adjustable by Dentist or Physician during the duration of use</th>
<th>Adjustable by Dentist or Physician during the duration of use</th>
<th>Adjustable by Dentist or Physician during the duration of use</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usage</td>
<td>Removable and Reusable by the same patient.</td>
<td>Removable and Reusable by the same patient.</td>
<td>Removable and Reusable by the same patient.</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td>Night Time Usage Only</td>
<td>Night Time Usage Only</td>
<td>Night Time Usage Only</td>
<td></td>
</tr>
<tr>
<td>Biocompatible</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>OTC or Rx</td>
<td>Rx</td>
<td>Rx</td>
<td>Rx</td>
<td>Same</td>
</tr>
</tbody>
</table>

### Device Technological Differences

<table>
<thead>
<tr>
<th>Connectors</th>
<th>Consists of an upper and lower appliance that are 2 separate appliances that work in conjunction with each other -</th>
<th>Consists of an upper and lower appliance that are connected together with a plastic connector - limits the jaw movement to opening and closing only</th>
<th>Consists of an upper and lower appliance that are connected together with a metal spring - limits the jaw movement to opening and closing only</th>
<th>2 separate appliances allows for 3 dimensional freedom of movement of the lower jaw and incurs no additional risk to the patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion</td>
<td>2 piece design allows for the upper appliance to be inserted first followed by the lower appliance</td>
<td>the upper and lower appliance to be inserted at the same time</td>
<td>the upper and lower appliance to be inserted at the same time</td>
<td>Two piece design allows greater ease of insertion and incurs no additional risk to the patient</td>
</tr>
<tr>
<td>Fabrication</td>
<td>Hand made from acrylic and wire formation</td>
<td>Computer generated –</td>
<td>Hand waxed and metal casted</td>
<td>Hand made component exists in the TheraSom</td>
</tr>
</tbody>
</table>
milled from acrylic

device and a similar acrylic material is used in the OptiSleep device neither of these variations incur additional risk to the patients than are already present in the currently marketed devices.

| Retention | Upper appliance has acrylic coverage on the occlusal and mid buccal and lingual posterior teeth with retention clasp – Lower appliance has ball clasp retention from the buccal of the posterior teeth wrapping to the lingual with acrylic anterior lingual coverage | Upper and lower appliance has acrylic coverage on the buccal and lingual aspect of the teeth to the gum line | Upper appliance has metal casting that are formed around the height of contour of the cuspid and bicuspid teeth – Lower appliance and metal casting covering the occlusal surface of the premolars and molar teeth | The Kava and Kava with Herbst and OptiSleep both have acrylic coverage on commensurate dentition on the upper appliance and lower appliances the Kava and Kava with Herbst and the TheraSom device both utilize a metal casting in the lower appliance for retention incurring no additional risk to the patient than are already present in currently marketed devices |
9. Non-Clinical Performance Data

As part of demonstrating the substantial equivalence of the Kava and Kava with Herbst to the predicate/reference devices that are subject to this 510(k) submission, Sketchpad Innovations LLC completed a number of non-clinical performance tests, including:

Strength and elongation testing:

<table>
<thead>
<tr>
<th>#</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ASTM D-638-14 Standard Test Method For Tensile Properties of Plastics</td>
</tr>
<tr>
<td>2</td>
<td>ASTM D-790-10 Standard Test Methods for Flexure Properties of Unreinforced Plastics and Electrical Insulating Materials</td>
</tr>
<tr>
<td>3</td>
<td>ASTM D-792-13 Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement</td>
</tr>
</tbody>
</table>

The Kava and Kava with Herbst passed all the testing in accordance with internal requirements, applied national standards, and applied international standards shown below to support substantial equivalence of the subject device:

Biocompatibility - The biological safety of the components of the Kava and Kava with Herbst were evaluated in accordance with ISO 10993-1 and guidance document entitled Use of International Standard ISO-10993-1, “Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing within a Risk Management Process”. Under this, for the stated indications for use, each component of the device’s biological safety was evaluated for in vitro cytotoxicity, skin sensitization, and irritation, and mutagenicity and chemical characterization.

- Biocompatibility testing per ISO 10993-5 Cytotoxicity: Passed
- Biocompatibility testing HET-CAM Tests for irritation and skin sensitization: Passed
- Biocompatibility testing mutagenicity (Ames test): Passed
- Biocompatibility testing per ISO 10993-12 chemical analysis of eluted components acc.: Passed
Risk Analysis - Formal Risk Assessment of the Kava was performed in accordance with ISO 14971. With respect to perceivable conditions in which the device would be subjected to a worst-case environmental or human error scenario, Sketchpad Innovations LLC believes the outcomes of these risks are considered acceptable within the context of ISO 14971, and that all potential risks have been mitigated to the lowest form.

10. **Performance Testing Summary**

As part of demonstrating the substantial equivalence of the Kava and Kava with Herbst and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Sketchpad Innovations LLC completed a number of tests. The Kava and Kava with Herbst meet all the requirements for overall design, biocompatibility, and performance testing confirming that the output meets the design inputs and specifications. The Kava and Kava with Herbst passed all testing stated above as shown by the acceptable results obtained.

The Kava and Kava with Herbst complies with the applicable voluntary standards for biocompatibility per materials used. The device passed all the testing in accordance with national and international standards.

11. **Statement of Substantial Equivalence**

It has been shown in this 510(k) submission that the differences between the Kava and Kava with Herbst and the predicate device do not raise any different questions regarding its safety and effectiveness. The performance testing provided demonstrates that the subject device(s) is substantially equivalent to the predicate device and reference device. The Sketchpad LLC, Kava and Kava with Herbst, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.