Dear Panel Members and Consultants:

Thank you for agreeing to serve at our next meeting of the Dental Products Panel on October 11-12, 2005. The subjects for this two day meeting are recommendations on the classifications of seven pre-amendments dental devices and on the over-the-counter (OTC) use of dental mouth guards. By “pre-amendments” we mean the devices as they were on the market prior to the passing of the Medical Device Amendments of May 28, 1976. The seven pre-amendments devices are as follows:

- Artificial Saliva
- Retraction Cord
- Oral Wound Dressing
- Dental Electrical Anesthesia
- Root Canal Cleanser
- Root Apex Locator
- Dental Mouthguard.

The panel will be asked to make a recommendation on the class of regulatory control, i.e., Class I, II, or III, appropriate for the devices.

In addition, the FDA seeks the Panels recommendation on the over-the-counter use of dental mouthguards.

Please review the enclosed background information in preparation for the meeting. During the classification portion of the meeting you will be asked at the end of the discussion of each device to complete a “General Device Classification Questionnaire” and a “Supplemental Data Sheet.” Copies of these forms are included in this package. Please familiarize yourself with these forms. You will be asked to complete them for each of the seven devices discussed at the meeting.
Also included in this package are:

- A draft agenda for the meeting,
- Executive summary regarding the unclassified devices,
- Executive summary regarding the OTC use of dental mouthguards,
- The questions for panel consideration,
- Regulatory Class definitions,

As well as the

- Classification forms.

Please note that, immediately prior to the meeting, **there will be classification training from 8:00 to 9:00 a.m. in the Boardroom of the hotel on October 11, 2005. Attendance is required.**

FDA has provided you with information for the upcoming meeting of the Dental Products Panel. This information is for use by the panel during deliberations at the panel meeting. **You should not discuss this information with the sponsors associated with these devices, with members of the press or public, with financial institutions, or with any other person, including other Panel members.** If for any reason you are contacted by anyone seeking to obtain or discuss this information, you should refrain from any discussion and advise me immediately.

In addition, Panel members and consultants who voluntarily or by way of a homework assignment submit written analyses, comments, etc. to the agency should be aware that these submission may be **subject to release to the public**, including sponsors, by means of the Freedom of Information Act (Ref: CFR 20.80, 20.81, 20.84, 20.103). Thus, such submissions should only contain material that reflects the technical and scientific content of the subject being reviewed.

Due to the general nature of this meeting, you will not be required to return or destroy any of the material being sent to you in this package.

Please remember that this package will not be made public until one business day before the meeting, i.e., October 7, 2005. On this day the agenda, roster, and this package will be posted on the internet at [http://www.fda.gov/cdrh/panel](http://www.fda.gov/cdrh/panel). After the meeting the transcript and summary minutes will also be posted on this web site.
Please review the enclosed material. Please pay particular attention to your affiliation listed in the draft agenda. If there are any changes to your personal information please contact me. I may be reached at 301-827-5283, ext. 123., via fax at 301-480-3002, or via email at: michael.adjodha@fda.hhs.gov. I am in the office weekdays from 7:30 a.m. to 4:00 p.m., Eastern Time. Once again, thank you for agreeing to share your expertise with us.

Michael E. Adjodha, Executive Secretary

Dental Products Panel
Classification and General Issues Meeting

Contents:

Section 1: Draft Agenda

Section 2: Executive Summaries: Unclassified Devices

Section 3: Executive Summary: OTC Use of Dental Mouthguards

Section 4: Questions for the Panel to Consider

Section 5: Regulatory Class Definitions

Section 6: Classification Forms (For Reference)
Section 1: Draft Agenda
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
MEDICAL DEVICES ADVISORY COMMITTEE
MEETING OF THE
DENTAL PRODUCTS PANEL

MEETING AGENDA
11-12 October 2005

Hilton Washington DC North
Ballroom Salons A and B
Gaithersburg, Maryland
BACKGROUND

In accordance with 21 CFR 860.84, Classification Procedures for “Old Devices,” the Food and Drug Administration (FDA) has referred to the Dental Products Panel (the Panel) seven unclassified dental devices which were in commercial distribution before May 28, 1976. The Panel is asked to make a recommendation on the class of regulatory control, i.e., Class I, Class II, or Class III, appropriate for the devices.

In addition, FDA seeks the Panel’s recommendation concerning the over-the-counter (OTC) use of dental mouthguards. Excluded from consideration are mouthguards intended for non-therapeutic indications such as sports mouthguards which are intended to protect the teeth during contact sports. These products are regulated by the Consumer Product Safety Commission (CPSC).

PANEL ACTION

The Panel will discuss and make recommendations on the classification of the following unclassified dental devices:

- Root canal cleanser, product code KJJ, intended to cleanse and/or lubricate root canals after endodontic instrumentation;
- Retraction cord, product code MVL, intended for temporary retraction and hemostasis of the gingival margin;
- Root apex locator, product code LQY, intended to measure the length of a root canal by locating the apex of the tooth;
- Dental mouthguards, product code MQC, intended to provide therapeutic protection against tooth grinding, bruxism, and jaw clenching;
- Artificial saliva, product code LFD, intended for the relief of chronic and/or temporary xerostomia;
- Oral wound dressing, product code MGQ, intended as a physical barrier for the temporary protection of tissue and to provide pain relief;
- Dental electrical anesthesia, product code LWM, intended, through the application of electrical current, to provide analgesia or anesthesia during dental procedures.

Also, the Panel will discuss and make recommendations regarding the over-the-counter (OTC) use of dental mouthguards.
MEETING AGENDA
DENTAL PRODUCTS PANEL
11-12 October 2005

Hilton Washington DC North
Ballroom Salons A and B
Gaithersburg, Maryland

TUESDAY, 11 OCTOBER 2005

9:15 a.m. CALL TO ORDER
9:15 - 9:30 a.m. Welcome and Introductory Remarks
   • Dr. Jon B. Suzuki, Chairman
   • Mr. Michael E. Adjodha, Executive Secretary
   • CDRH Ethics Staff

9:30 - 10:00 a.m. FDA Presentations on the Critical Path to New Medical Devices and on Condition of Approval Studies
   • Dr. Sousan S. Altaie, Office of In Vitro Diagnostic Device Evaluation and Safety
   • Dr. Thomas P. Gross, Office of Surveillance and Biometrics
MEETING AGENDA
11 October 2005

10:00 - 10:30 a.m.  Open Public Hearing
Public attendees, who have contacted the Executive Secretary prior to the meeting, will address the Panel and present information relevant to the agenda. Speakers are asked to state whether or not they have any financial involvement with the product(s) or competing products being discussed.

10:30 - 10:45 a.m.  FDA Presentation – Meeting Overview
- Dr. M. Susan Runner, Chief, Dental Devices Branch
- Ms. Marjorie Shulman, Program Operations Staff, FDA

10:45 - 11:00 a.m.  BREAK

11:00 - 11:15 a.m.  FDA Presentation – Artificial Saliva
- Ms. Myra E. Browne, Biologist

11:15 - 11:30 a.m.  Open Comment

11:30 - 12:30 p.m.  Panel Recommendation on the Classification of Artificial Saliva
- Ms. Marjorie Shulman, Program Operations Staff, FDA

12:30 - 1:30 p.m.  LUNCH BREAK

1:30 - 1:45 p.m.  FDA Presentation – Retraction Cord
- Dr. Robert S. Betz, Dental Officer

1:45 - 2:00 p.m.  Open Comment

2:00 - 2:45 p.m.  Panel Recommendation on the Classification of Retraction Cord
- Ms. Marjorie Shulman, Program Operations Staff, FDA

2:45 - 3:00 p.m.  BREAK
MEETING AGENDA
11 October 2005

3:00 - 3:15 p.m.  FDA Presentation – Oral Wound Dressing
  • Ms. Angela E. Blackwell, Biomedical Engineer

3:15 - 3:30 p.m.  Open Comment

3:30 - 4:15 p.m.  Panel Recommendation on the Classification of Oral Wound Dressing
  • Ms. Marjorie Shulman, Program Operations Staff, FDA

4:15 - 4:30 p.m.  FDA Presentation – Dental Electrical Anesthesia
  • Mr. Andrew I. Steen, Mechanical Engineer

4:30 - 4:45 p.m.  Open Comment

4:45 - 5:30 p.m.  Panel Recommendation on the Classification of Dental Electrical Anesthesia
  • Ms. Marjorie Shulman, Program Operations Staff, FDA

5:30 p.m.  BREAK – reconvene the next day at 8:00 a.m.
MEETING AGENDA

Wednesday, 12 OCTOBER 2005

8:00 a.m. MEETING RECONVENES

8:00 - 8:15 a.m. FDA Presentation – Root Canal Cleanser
  • Ms. Myra E. Browne, Biologist

8:15 - 8:30 a.m. Open Comment

8:30 - 9:15 a.m. Panel Recommendation on the Classification of Root Canal Cleanser
  • Ms. Marjorie Shulman, Program Operations Staff, FDA

9:15 - 9:30 a.m. BREAK

9:30 - 9:45 a.m. FDA Presentation – Root Apex Locator
  • Mr. Michael J. Ryan, Biomedical Engineer

9:45 - 10:00 a.m. Open Comment

10:00 - 10:45 a.m. Panel Recommendation on the Classification of Root Apex Locator
  • Ms. Marjorie Shulman, Program Operations Staff, FDA

10:45 - 11:00 a.m. FDA Presentation – Dental Mouthguard
  • Dr. Kevin P. Mulry, Dental Officer

11:00 - 11:15 a.m. Open Comment

11:15 - 12:00 p.m. Panel Recommendation on the Classification of Dental Mouthguard
  • Ms. Marjorie Shulman, Program Operations Staff, FDA

12:00 - 1:00 p.m. LUNCH BREAK
MEETING AGENDA
12 October 2005

1:00 - 1:30 p.m. Open Public Session
This portion of the meeting is open to public observers. Public observers may not participate except at the specific request of the Chairperson.

1:30 - 2:00 p.m. FDA Presentation – General Issues: OTC Use of Dental Mouthguards
- Dr. Kevin P. Mulry, Dental Officer

2:00 - 3:00 p.m. Open Comment

3:00 - 3:15 p.m. BREAK

3:15 - 4:15 p.m. Panel Discussion and Recommendation

4:15 - 4:20 p.m. FDA Presentation

4:20 p.m. MEETING ADJOURNED
## DENTAL PRODUCTS PANEL
### 11-12 October 2005

<table>
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<th>CHAIRMAN</th>
<th>EXECUTIVE SECRETARY</th>
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| Jon B. Suzuki, DDS, PhD, MBA  
Associate Dean  
Temple University,  
School of Dentistry  
Philadelphia, Pennsylvania | Michael E. Adjodha, MChE  
Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Division of Anesthesiology, General Hospital,  
Infection Control, and Dental Devices (DAGiD) |

### PANEL MEMBERS AND CONSULTANTS

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<tr>
<th>Name</th>
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| Salomon Amar, DDS, PhD| Professor, Periodontology  
Boston University, School of Dental Medicine  
Boston, Massachusetts | Member                |
| Leif K. Bakland, DDS  | Professor, Endodontics  
Loma Linda University, School of Dentistry  
Loma Linda, California | Consultant            |
| David L. Cochran, DDS, PhD | Professor and Chairman, Periodontology  
University of Texas, Health Science Center  
San Antonio, Texas | Member                |
| B. Gail Demko, DMD    | Dentist  
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| Elizabeth S. Howe     | President  
Nonprofit Consultants  
Auburn, Washington | Member  
Consumer Representative |
| William J. O’Brien, MS, PhD | Professor, Materials Science  
University of Michigan, School of Dentistry  
Ann Arbor, Michigan | Member                |
| Daniel R. Schechter, JD | General Counsel  
Parkell, Incorporated  
Farmingdale, New York | Member  
Industry Representative |
| Domenick T. Zero, DDS, MS | Professor and Chairman, Preventative Dentistry  
Indiana University, School of Dentistry  
Indianapolis, Indiana | Member                |
| John R. Zuniga, PhD, DMD | Professor and Graduate Program Director, Oral Surgery  
University of North Carolina, School of Dentistry  
Chapel Hill, North Carolina | Member                |
### Other Meeting Participants

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<th>FDA - DAGID</th>
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Draft Questions for Panel Consideration

Under Section 502(f)(1) of the FD&C Act, devices not exempt from this section shall bear “adequate directions for use.” Over-the-counter (OTC) devices are subject to this section. Regarding the OTC use of dental mouthguards, please address the following questions:

1) Can adequate directions for use be written such that lay persons may:
   • diagnose their oral health status?
   • determine their need for dental mouthguards?
   • determine their need for a particular design of mouthguards, e.g., soft, hard, full coverage, partial coverage, etc?

If yes, please proceed to the other questions. If no, please discuss your reasons why adequate directions for use cannot be written for the lay person and, thus, why OTC use cannot be supported. End here.

2) If OTC use is supported, are there any designs or types you believe should be excluded from an OTC indication?

3) Of the dental mouthguard designs supported for OTC use, please recommend the following regarding the device’s labeling. What information should be provided to help the lay user:
   • determine the need for the device?
   • ascertain the proper fitting of the device?
   • select an appropriate design?
   • be aware of the contraindications?

4) Do you believe a clinical study is needed to support an OTC indication for dental mouthguards? If no, please discuss your reasons. If yes, please discuss the following aspects of the study needed:
   • study design
   • endpoints
   • adverse events that would be considered significant.
Section 2: Executive Summaries:
Unclassified Devices
Artificial Saliva: Executive Summary

Device Description:

Artificial saliva is used for the relief of xerostomia which may result from an illness, chemotherapy, radiation, stress or aging.

Indication for Use:

Artificial saliva is used to mimic natural saliva for the temporary relief of chronic and/or temporary xerostomia.

Generic Type of Device:

Therapeutic device

Device History:

Artificial saliva has been on the market since the 1970’s. The original artificial saliva products on the market were sprays and solutions composed of components used to increase viscosity such as carboxymethylcellulose or hydroxyethylcellulose, minerals such as calcium and phosphate ions and fluoride, preservatives and flavorings. Recently 510(k)’s have been cleared with different delivery systems and formulations, such as gels, lozenges, and lipid based solutions. These devices have been cleared for OTC or prescription use.

Adverse Event Reports:

None were reported

Risks to Health and Mitigations:

The risks to health are: adverse tissue reactions and improper use.

These risks are mitigated by: labeling, chemical composition information, and biocompatibility testing.
Gingival Retraction Cord:
Executive Summary

Device Description:

- Twine like strands of cotton or cotton/polyester fibers of various sizes or diameters.
  - Single stranded, or multiple strands
  - Twisted, braided, or knitted.
- Inserted into the gingival sulcus of teeth for several minutes and removed immediately prior to placement of impression material on tooth surfaces.

Indications for Use:

Gingival retraction cords are used as an aid in the taking of dental impressions to assure capture of subgingival preparation margins.

Generic Type of Device:

Surgical Device.

Device History:

The gingival retraction cord was on the U. S. market before May 28, 1976. Retraction cords were supplied with and without a drug component. The drug components were epinephrine and aluminum chloride. Later, additional drug components such as ferric sulfate and zinc phenosulfate were used in place of epinephrine and aluminum chloride.

Adverse Event Reports:

One Medical Device Report (MDR) has been submitted for the gingival retraction cord. In 1006, one patient developed syncopical symptoms (elevated blood pressure, elevated heart rate, and dizziness) related to the presence of the epinephrine (1.15 mg/inch). She was taken to a trauma center where she was observed for 3 hours. No treatment was rendered.

Risks to Health and Mitigations:

Two risks to health have been identified:
- Adverse tissue reaction may occur to retraction cord material and/or drug component. The mitigation is a guidance document where materials specifications, device labeling, and biocompatibility testing are addressed. In addition FDA will use drug consults to address drug issues that may arise.
- There are risks associated with improper use of this device, which include inhaling the retraction cord material and gingival recession when excessive force is used in cord placement. The mitigation identified to address these risks is adequate device labeling.
Oral Wound Dressing: Executive Summary

**Device Description:**

Oral wound dressings are physical barriers such as hydrogels, resins, and polymers for temporary protection of tissue. This physical barrier function may provide a measure of pain relief and protection from oral debris.

Oral wound dressings may contain a drug but the primary mode of action is provided by the physical barrier property of the device component. Drug or biological components will require consultation from CDER or CBER.

**Indications for Use:**

Oral wound dressings are intended as a physical barrier for temporary protection of tissue and to provide pain relief.

**Generic Type of Device:**

Therapeutic device

**Device History:**

Oral wound dressings were used in the practice of dentistry before 1976. Oral wound dressings have been cleared for prescription indications in conjunction with periodontal surgery or post radiation therapy pain relief. OTC oral wound dressings have been cleared for relief of pain associated with oral appliances, apthous ulcers, and other oral wounds. Examples of devices on the market then are the original Orabase, Orabase with Kenalog, and Coe Pak.

15 510(k)s have been received for oral wound dressings.
- 1 as a dental cement used as a tissue covering
- 4 as periodontal wound dressings
- 10 as unclassified hydrogel wound dressings containing drugs or biologics.

**Adverse Event Reports:**

- 9 reports of allergic reactions
- 1 report of adhering mucosal tissue to a tooth
Risks to Health and Mitigations:

The risks to health are adverse tissue reactions, adhesion of tissues, and improper use.

These risks are mitigated by biocompatibility testing, preclinical testing, and labeling.
Dental Electrical Anesthesia: Executive Summary:

Description:

Dental Electrical Anesthesia devices provide an electrical current for analgesia and anesthesia during dental procedures. These devices are powered by either an AC or DC power source and supply a current to the intended area by a direct connection to the oral tissue. These devices are connected to the patient prior to the beginning of the procedure and removed just after procedure completion. During that time, the applied current produces the required anesthetic effect. This device is intended to be used in place of or in conjunction with injectable anesthesia.

Indications for Use:

Dental electrical anesthesia is intended, through the application of electrical current, to provide analgesia or anesthesia during dental procedures.

Generic Type of Device:

Surgical Device

Device History:

Dental Electrical Anesthesia devices were on the market before the enactment of the Medical Device Act of 1976. They have been regulated as unclassified devices via the 510(k) process. To date, fifteen devices have been cleared for marketing.

Adverse Event Reports:

There were nine reported adverse events:

3 skin burns at electrode application site
4 after use permanent/temporary nerve damage
1 seizure
1 skin reaction to electrode

Risks to Health and Mitgations:

Dental Electrical Anesthesia devices present a number of risks to health. These devices provide electrical current to the nerve through the oral mucosa and thus introduce the chance of skin and other tissue trauma via burns and electrical shock. Patients with pacemakers are also put at risk for electromagnetic interference. Other risks include:
infection through the multiple use electrodes, adverse tissue reactions to the electrode material, or pain caused by the procedure itself through an inoperative device.

We believe these risks can be mitigated by preclinical testing, sterility controls and labeling. Infection and tissue biocompatibility issues are covered by sterility and biocompatibility testing. Pain will be mitigated by labeling concerning proper use. EMI and device failure are diminished by preclinical testing as provided by IEC 60601-2-10 (International standard for requirements for safety of nerve and muscle stimulators)
Root Canal Cleanser: Executive Summary

Device Description:
Root canal cleansers are applied directly into the pulp chamber and may remove calcifications and lubricate the canal to permit efficient instrumentation.

Indication for Use:
Root canal cleansers are intended to clean and lubricate the root canal during endodontic treatment.

Generic Type of Device:
Surgical device

Device History:
Root canal cleansers were on the market prior to 1976. Over the years the ingredients have evolved for cleaning and disinfecting the root canal. These components include EDTA, carbamide peroxide, and quaternary ammonium compounds. CDRH has cleared one root canal cleanser that contains the antimicrobial agent, doxycycline. Antimicrobial indications for this cleanser resulted in a consultation with CDER.

Adverse Event Reports:
None were reported.

Risks to Health and Mitigations:
The risks to health are adverse tissue reaction to any of the components in the device and improper use of the device.

These risks are mitigated by labeling, complete chemical composition information, and biocompatibility testing.
Root Apex Locator: Executive Summary

Device Description:

A root apex locator consists of a power source, a lip clip electrode, a metal root canal probe, and a display unit. The lip clip is hooked to the side of a patient’s mouth, and the root canal probe is placed in the patient’s root canal. The power source applies a current to both, and the patient’s oral tissue forms a complete circuit. The locator device measures the impedance between the lip and the probe. The impedance between the lip and the root apex is a known value, so as the probe moves through the canal, the different impedance values are measured and displayed as root canal positions.

Indications for Use:

Root apex locators are intended to measure the working length of a patient’s root canal.

Generic Type of Device:

Surgical

Device History:

Eighteen 510(k) Pre-Market Notifications have been received for root apex locators, dating from 1986 – 2003. The earliest submission refers to root apex locators that have been on the market since at least 1976 as predicate devices.

Adverse Event Reports:

None were reported

Risks to Health and Mitigations:

Root apex locators present the following risks to health:

- Electrical shock – These devices introduce an electrical current to the patient’s oral tissue. A large amount of current could induce an electrical shock. Adverse events such as spills may also cause hazardous malfunctions of the device.

- Electromagnetic interference (EMI) – An environment with multiple electronic devices can be subject to electromagnetic interference between devices. Electromagnetic interference may in turn cause device malfunctions.

- Sterility – Root apex locators are reusable; each device is intended to be used with multiple patients, therefore, each device has the potential to carry bacteria and disease between patients.
• Adverse tissue reactions – Any foreign material or device introduced to the body has the risk of inducing biocompatibility problems such as irritation, cytotoxicity, etc.

• Improper use – Incorrect use of root apex locators may be responsible for patient pain or incorrect measurement of the root canal working length, which may lead to further problems in endodontic procedures.

The following mitigations are essential to prevent the aforementioned risks to health:

• Electrical shock – Consistent design specifications will assure that the current used in root apex locators will be below dangerous levels. Voluntary standards such as IEC 60601 contain appropriate preclinical testing that will assure the electrical safety of the device from misuse and adverse events.

• Electromagnetic interference (EMI) – Electromagnetic interference may be prevented by proving electromagnetic compatibility (EMC). Voluntary standards such as IEC 60601 address this adequately.

• Sterility – Labeling should address the sterilization of the device between patients. As is recommended in CDRH Bluebook Memorandum K90-1, the recommended sterilization protocols should be validated according to an FDA – recognized standards, such as ISO 11134 for moist heat sterilization, and ISO 11135 for ethylene oxide sterilization.

• Adverse tissue reactions – Biocompatibility problems can be prevented by conformance with relevant standards such as ISO 10993 and ISO 7405.

• Improper Use – Improper use can be avoided by clear and descriptive labeling and prescription use only designation of root apex locators.
**Dental Mouthguard: Executive Summary**

**Device Description:**

A dental mouthguard is an intraoral device fabricated from hard or soft acrylic that is intended for therapeutic protection against tooth grinding, bruxism, and jaw clenching that may be associated with TMD syndrome/orofacial pain. Mouthguards also provide short-term pain relief from muscle spasm associated with occlusal interference, and can be associated with increased muscular activity.

**Indications for Use:**

A dental mouthguard is an intraoral device intended to provide therapeutic protection against tooth grinding, bruxism, or jaw clenching that may result in orofacial pain.

**Generic Type of Device:**

Therapeutic device

**Device History:**

Mouthguards have been custom fabricated by dentists in their offices since at least the 1940’s. The mouthguards were full arch coverage devices custom made by applying acrylic resin to stone casts of the patient’s teeth. They also were fabricated on a stone model by the utilization of a hard or soft acrylic sheet and vacuum forming it onto the stone model of the patient’s teeth. More recent devices are fabricated from materials such as thermoformed acrylic or are pre-fabricated. We have cleared approximately eight 510(k)s that are all prescription devices.

**Adverse Event Reports:**

There has been only one MDR for dental mouthguards which resulted from a packaging issue.

**Risks to Health and Mitigations:**

Risks to health posed by mouthguards include adverse tissue reactions which may be mitigated by the use of biocompatibility testing and labeling. Standards that apply to biocompatibility testing of mouthguards include ISO 10993 and ISO 7405. Other risks to health include: jaw pain, teeth pain, joint noises, and loosening or shifting of the teeth or a change in bite that lasts longer than a few minutes. A mitigation for these risks is labeling which includes a specification for prescription use and therefore assumes a competent intervention on behalf of the patient.
Section 3: Executive Summary: OTC Use of Dental Mouthguards
Over-the-counter (OTC) Use of Dental Mouthguards --
Executive Summary

A dental mouthguard is an intraoral device intended to provide therapeutic protection against tooth grinding, bruxism, or jaw clenching that may result in orofacial pain. Dental mouthguards are unclassified devices listed under procode MQC. Sponsors need to submit a 510(k) (premarket notification) for marketing clearance for all dental mouthguards.

To date, all dental mouthguards have been cleared as prescription devices, however, some sponsors have requested that these devices be made available OTC. The Panel meeting is intended to discuss general issues surrounding the prescription use versus over the counter (OTC) use of dental mouthguards. The discussion will include the role of the dentist in the diagnosis, treatment, and follow-up to fabrication and delivery of the mouthguard; the ability of the patient to self diagnose, select, and fit a mouthguard; the types of clinical data that would be needed to support an OTC intended use; and the components of adequate device labeling.
Section 4: Draft Questions for Panel Consideration
Draft Questions for Panel Consideration

Under Section 502(f)(1) of the FD&C Act, devices not exempt from this section shall bear “adequate directions for use.” Over-the-counter (OTC) devices are subject to this section. Regarding the OTC use of dental mouthguards, please address the following questions:

1) Can adequate directions for use be written such that lay persons may:
   - diagnose their oral health status?
   - determine their need for dental mouthguards?
   - determine their need for a particular design of mouthguards, e.g., soft, hard, full coverage, partial coverage, etc?

   If yes, please proceed to the other questions. If no, please discuss your reasons why adequate directions for use cannot be written for the lay person and, thus, why OTC use cannot be supported. End here.

2) If OTC use is supported, are there any designs or types you believe should be excluded from an OTC indication?

3) Of the dental mouthguard designs supported for OTC use, please recommend the following regarding the device’s labeling. What information should be provided to help the lay user:
   - determine the need for the device?
   - ascertain the proper fitting of the device?
   - select an appropriate design?
   - be aware of the contraindications?

4) Do you believe a clinical study is needed to support an OTC indication for dental mouthguards? If no, please discuss your reasons. If yes, please discuss the following aspects of the study needed:
   - study design
   - endpoints
   - adverse events that would be considered significant.
Section 5: Regulatory Class Definitions
Regulatory Class Definitions

Class I

Class I devices are those for which general controls are sufficient to provide reasonable assurance of the safety¹ and effectiveness² of such devices.

General controls include:

- Establishment Registration of companies which are required to register under 21 CFR Part 807.20, such as manufacturers, distributors, repackages and relabelers. Foreign establishments, however, are not required to register their establishments with FDA.
- Medical Device Listing with FDA of devices to be marketed.
- Labeling devices in accordance with labeling regulations in 21 CFR Part 801 or 809.
- Submission of a premarket notification \([510(k)]\) before marketing a device.

Note that most Class I devices are exempt from the premarket notification and/or GMP regulation.

¹ There is a reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from the use of the device for its intended uses and conditions for use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of the device shall adequately demonstrate the absence of unreasonable risk associated with the use of the device for its intended uses and conditions for use.

² There is a reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Valid scientific evidence includes:
- Well-controlled investigations
- Partially controlled studies
- Studies & objective trials without matched controls
- Well-documented case Histories by qualified experts
- Reports of significant human experience with a marketed device
Class II

Class II devices are those which cannot be classified into Class I because general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of such devices but for which there is sufficient information to establish special controls to provide such assurance:

Special Controls include:

- Performance Standards
- Postmarket Surveillance
- Patient Registries
- Development and dissemination of guidelines/guidances
- Design Controls
- Recommendations and other appropriate actions such as special labeling requirements.
- Tracking Requirements

Most Class II devices are subject to premarket notification [(510(k)].
Class III

Class III devices are those for which insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of such devices and that such devices are:

- life sustaining or life supporting
- of substantial importance in preventing impairment of human health, or
- present unreasonable risk of illness or injury.

Class III devices generally require premarket approval (PMA). Devices which require an approved PMA to be marketed are those:

- regulated as new drugs prior to May 28, 1976, also called transitional devices
- devices found not substantially equivalent to devices marketed prior to May 28, 1976
- Class III preamendment devices which, by regulation in 21 CFR, require a premarket approval application

There are limited Class III devices which can be marketed with a premarket notification [510(k)]. These are:

- postamendment (i.e., introduced to the U.S. market after May 28, 1976) Class III devices which are substantially equivalent to preamendment (i.e., introduced to the U.S. market before May 28, 1976) Class III devices and for which the regulation calling for the premarket approval application (PMA) has not been published in 21 CFR.
Section 6: Classification Forms