Guidance for Industry and FDA Staff

Dental Handpieces - Premarket Notification [510(k)] Submissions

Document issued on: May 2, 2007

This guidance supersedes "Guidance Document on Dental Handpieces" issued July 1995

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

FDA has developed this guidance document to assist industry in preparing premarket notification submissions (510(k)s) for dental handpieces intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth. (21 CFR 872.4200). This guidance supersedes the document entitled**, Guidance Document on Dental Handpieces** issued July 1995. It updates the references and clarifies the recommendations.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at http://www.fda.gov/cdrh/modact/leastburdensome.html.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Background

A manufacturer who intends to market a device of this generic type must conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the act), including the premarket notification requirements described in 21 CFR 807 Subpart E, and obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.81 and 807.87).

This guidance document identifies the classification regulations and product codes for dental handpieces (refer to **Section 4. Scope)**. In addition, other sections of this guidance document provide additional information to manufacturers on addressing risks related to these devices in premarket notifications (510(k)s).

This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87, the guidance, **Format for Traditional and Abbreviated 510(k)s**[1] and the section of CDRH's Device Advice, **How to Prepare a 510(k) Submission**.[2]

Under **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**,[3] a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA has issued a guidance document addressing that device. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this guidance document was used during the device development and testing and should briefly describe the methods or tests used. We recommend that you also include a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 21 CFR 807.87, as well as some other items that we recommend you include in an Abbreviated 510(k).

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[1] http://www.fda.gov/cdrh/ode/guidance/1567.html.
[2] http://www.fda.gov/cdrh/devadvice/314.html.
[3] http://www.fda.gov/cdrh/ode/parad510.html.

A. Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this guidance document.

B. Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Please refer to **Section 10. Labeling** for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

C. Summary report

We recommend that the summary report contain:

Description of the device and its intended use

We recommend that you describe the performance specifications and, when appropriate, include detailed, labeled drawings of the device. (Please refer to **Section 5**. **Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.[4]

Description of device design

We recommend that you include a brief description of the device design requirements.

Identification of the risk analysis method

We recommend that you identify the risk analysis method(s) you used to assess the risk profile, in general, as well as the specific device's design and the results of this analysis. (Please refer to **Section 6. Risks to Health** for the risks to health generally associated with the use of this device that FDA has identified.)

Discussion of the device characteristics

We recommend that you discuss the device characteristics that address the risks identified in this guidance document, as well as any additional risks identified in your risk analysis.

[4] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

Description of the performance aspects

We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 8-10** of this guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[5]

Reliance on standards

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either:

- a statement that testing will be conducted and meet specified acceptance criteria before the device is marketed; or
- a declaration of conformity to the standard.[6]

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing which the standard describes. For more information, please refer to section 514(c)(1)(B) of the Act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations**.[7]

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

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[5] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[6] See **Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(k)] Submissions)**, http://www.fda.gov/cdrh/ode/reqrecstand.html.

[7] http://www.fda.gov/cdrh/ode/guidance/1131.html.

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering certain modifications to their own cleared devices should consider submitting Special 510(k)s.

In general, the discussion above applies to any 510(k). The following is a specific discussion of how you should apply this guidance document to a premarket notification submission for dental handpieces.

4. Scope

The scope of this guidance is limited to the Class I device described below, 21 CFR 872.4200, which includes the product codes listed in the table below.

21 CFR 872.4200 Dental handpiece and accessories

A dental handpiece and accessories is an AC-powered, water-powered, air-powered, or belt-driven, hand-held device that may include a foot controller for regulation of speed and direction of rotation or a contra-angle attachment for difficult to reach areas intended to prepare dental cavities for restoration, such as fillings, and for cleaning teeth.

The scope of this guidance includes air-powered high speed handpieces, air-powered micromotors, contra-angle attachments, straight attachments and oscillating endodontic contra-angles. This document also includes AC-powered handpiece systems that utilize a controller console, foot control, DC-powered micromotor, and lubricants.

Procode	Device
EBW	Controller, Foot, Handpiece and Cord
EKX	Handpiece, Direct Drive, AC-Powered
EFB	Handpiece, Air-Powered, Dental (includes lubricants)
EFA	Handpiece, Belt And/Or Gear Driven, Dental
EGS	Handpiece, Contra- And Right-Angle Attachment, Dental
EKY	Handpiece, Water-Powered
NYL	Handpiece, Air-Powered, Root Canal Irrigation

The scope of this guidance does not include:

- burs**,** mandrels, and other cutting attachments that are designed to be mounted in the chucks of handpieces (21 CFR 872.3240)
- surgical bone saws and accessories (21 CFR 872.4120)

5. Device Description

We recommend you identify your device by regulation number and product code identified in **Section 4. Scope** and include a description of:

- the principles of operation (i.e., the scientific principles behind how the device achieves its intended use)
- any accessories that are to be used with the system.

We recommend you provide information to show how the new device is both similar to and different from the legally marketed device. Side by side comparisons, whenever possible, are desirable; for example, using a tabular format as shown below. We also recommend that you describe how any differences may affect the comparative safety and effectiveness of your device.

Table 1: Device and Predicate Comparison Table

Descriptive Information	Device	Predicate
Indication for Use		
Device Design – i.e., operational modes, air/water ports, fiberoptics, dimensions, type of chuck, coupling dimensions, and accessories		
Composition of Materials – including chemical composition of the waterlines and the patient-contacting portions of the device		
Technical Specifications – including chuck design, light intensity, bur extraction force, maximum air/water pressure, speed in rpms, and conformance with standards for shanks, coupling dimensions, and hose connections		
Lubricant – including legally-marketed lubricant (identify 510(k)), or chemical composition (including propellant, if applicable) with biocompatibility for lubricant not previously cleared through 510(k)		

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of dental handpieces, including lubricants and accessories, addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis to identify any other risks specific to your device, and include the results of this analysis. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Table 2. Risks and Mitigation Measures

Identified Risk	Recommended Mitigation Measures
Cross-contamination	Section 10. Labeling
Device malfunction	Section 7. Performance Testing
Electrical injury	Section 8. Electrical Safety and Electromagnetic Compatibility
Thermal injury	Section 7. Performance Testing Section 10. Labeling
Adverse tissue reaction	Section 9. Biocompatibility (for each component and/or accessory)
Improper use and maintenance	Section 10. Labeling
Electromagnetic interference	Section 8. Electrical Safety and Electromagnetic Compatibility

7. Performance Testing

We recommend that you evaluate your dental handpiece using the following FDA recognized standards or equivalent methods:

- ISO 7785-1 High-speed Air Turbine Handpieces
- ISO 7785-2 Straight and Geared Angle Handpieces
- ISO 1797 Dental Rotary Instruments – Shanks
- ISO 3964 Dental Handpieces – Coupling Dimensions
- ISO 9168 Dental Handpieces – Hose Connections
- ISO 9687 Dental Equipment – Graphical Symbols
- ISO11498 Dental Handpieces: Dental Low Voltage Electrical Motors

- ISO 13294 Dental Handpieces – Dental Air-Motors

In addition, we recommend that you describe:

- components with dimensions, including engineering drawings
- material composition of all components (include specifications or standards)
- features, including air/water spray, fiberoptics, etc.
- maximum operating air pressure in pounds per square inch (psi)
- range of speed in rotations per minute (rpm)
- coolant mechanism
- testing conducted to demonstrate the effect of sterilization cycles on handpiece performance
- type of chuck
- bur release force in Newtons (N)
- lubricant delivery system (i.e., spray can, pump)
- types of connectors
- shank length in millimeters (mm).

If your dental handpiece is controlled by computer software, we recommend that you submit the information for software-controlled devices described in **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices**.[8] The information we recommend you submit is determined by the "level of concern," which is related to the risks associated with software failure. The level of concern for a device may be minor, moderate, or major.

We recommend you demonstrate that the use of your device does not present a thermal hazard to the patient or the operator and describe the handpiece maintenance procedures to prevent overheating of the handpiece. For example, you may wish to demonstrate that patient contacting portions of the device do not present a thermal hazard.

8. Electrical Safety and Electromagnetic Compatibility

We recommend you demonstrate the electrical safety of your device by following the FDA-recognized standard below or equivalent methods:

- IEC 60601-1:1988, Medical Electrical Equipment – Part 1: General requirements for safety

We recommend you demonstrate the electromagnetic compatibility (EMC) of your device by following the recommendation of the FDA-recognized standard below or equivalent methods:

[8] http://www.fda.gov/cdrh/ode/guidance/337.html

- IEC 60601-1-2:1993, Medical Electrical Equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and test.

9. Biocompatibility

FDA recommends that you conduct biocompatibility testing as described in the FDA-modified **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing**,[9] for limited contact with mucosal tissue. We recommend that you select biocompatibility tests appropriate for the duration and level of patient contact with your device. For some devices, **ISO 7405:1997, Dentistry – Preclinical Evaluation of Biocompatibility of Medical Devices Used in Dentistry – Test Methods for Dental Materials**,[10] may contain appropriate test methods. If identical materials and identical material processing are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of providing biocompatibility testing.

10. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR Part 801.[11] We recommend labeling include:

- maximum speed in rotations per minute (rpm)
- types of connectors
- type of chuck
- warnings about thermal hazards
- maintenance requirements
- warnings about lubricant hazards (spray can labeling and packaging should comply with other Federal requirements for transport and use).
- operative speeds with gear reduction ratios.

Dental handpieces are generally provided to the user as nonsterile devices. Dental handpieces, including the micromotors, should be sterilized before the first use and between each patient use. We recommend that you provide instructions for the user on how to sterilize the handpiece. The instructions should include the method of sterilization and the cycle parameters, including the time, temperature and pressure. We

[9] http://www.fda.gov/cdrh/g951.html.
[10] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.cfm?ID=1405
[11] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

recommend that the labeling and instructions for use of your device follow the recommendations of the FDA guidance: **Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance**.[12] In particular, the instructions for reprocessing[13] should include details for the user on:

- disassembly
- cleaning
- lubrication
- sterilization[14]
- drying
- reassembly of the device
- use of disposable sheathing for other portions of the system.

Your 510(k) should identify the method that you used to validate the sterilization instructions.

[12] http://www.fda.gov/cdrh/ode/198.pdf.

[13] See also Center for Disease Control and Prevention's **Guidelines for Infection Control in Dental Health-Care Settings – 2003** for information about infection control in dental settings, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5217a1.htm.

[14] http://www.fda.gov/cdrh/comp/589.pdf.