This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

GUIDANCE DOCUMENT

ON

DENTAL HANDPIECES

DRAFT: July 1995

I. Introduction

A. Background

This guidance document is intended to facilitate the 510(k) review process for dental handpieces. By understanding what information is needed for a complete submission, industry and FDA will be able to complete the review process consistently, harmoniously, and with a minimal number of requests for additional information.

This guidance document contains elements which address the performance characteristics of handpieces. Although the user is able to evaluate many of these subjectively, it is prudent to include them for two reasons: they are an important indicator of the safety associated with mechanical integrity and they help FDA to evaluate the ability of the handpiece to withstand infection control procedures.

FDA recommends that reusable handpieces be heat sterilizable. There are two aspects of this requirement. The device must be designed to allow complete sterilization by a readily available method. In addition, the device must continue to perform, as labeled, in a manner that is substantially equivalent to that of legally marketed devices. The performance characteristics listed in this document will permit FDA to evaluate the ability of the device to remain substantially equivalent in safety and effectiveness after repeated sterilization procedures.

B. Scope

This document offers guidance to applicants of 510(k) submissions for powered rotary handpieces for use in the clinical practice of dentistry. These include air-powered high speed handpieces, air-powered low speed micromotors, contra-angle attachments, straight attachments and oscillating endodontic contra-angles. This document also covers AC-powered handpiece systems which utilize a controller console, foot control and DC-powered micromotor.

Exclusions

This guidance document does not cover:

1. Air compressors, air driers, water supplies, dental units, lamps, and hose fittings which are intended to deliver a regulated supply of air, water, and possibly electricity and fiberoptically transmitted light to handpieces

2. Burs, diamond-coated stones, mandrels, and other cutting attachments which are designed to be mounted in the chucks of handpieces

3. Bonesaws

4. Nitrogen driven surgical handpieces

5. Handpieces and handpiece systems intended exclusively for use in dental laboratories

C. Classification of Handpieces

21 CFR 872.4200 Dental handpiece and accessories

(a) *Identification.* A dental handpiece and accessories is an AC-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 restorations, such as fillings, and for cleaning teeth.

(b) *Classification.* Class I

II. Documentation

A. Reference to Standards, Practices, Technical Reports, Guidelines, and Test Methods. Identify all published standards, practices, technical reports, guidelines, codes and test methods upon which the design, labeling and testing of the handpiece are based. The following documents provide a significant amount of information on dental handpieces and infection control practices, and have been used as references in developing this guidance:

1. Disinfection, Sterilization and Preservation, 4th ed. 1991. Seymour S. Block, Lea and Febiger, Philadelphia.

2. AAMI TIR No. 12-1994. Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers.

3. ANSI/AAMI ST32-1991. Guideline for Gamma Radiation Sterilization.

4. Office of Device Evaluation Guidance Memorandum: 510(k) Sterility review guidance (enclosed).

5. ISO Standards applicable to dental handpieces:

7785-1	High-speed air-turbine handpieces
7785-2	Straight and geared angle handpieces

1797	Dental Rotary Instruments - Shanks
3964	Dental Handpieces - Coupling Dimensions
9168	Dental Handpieces - Hose Connections
9687	Dental Equipment - Graphical Symbols

6. UL Standards applicable to dental handpieces:

544	Professional Medical and Dental Equipment
2601-1	Standard for Medical Electrical Equipment, General Requirements for Safety (IEC 601-1 with U.S. deviations)

7. International Electrotechnical Commission (IEC):

601-1	Medical Electrical Equipment, General Requirements for Safety

8. "Acceptance Program Guidelines for High-Speed Handpieces." American Dental Association, Council on Dental Materials, Instruments and Equipment.

9. "Recommended Infection-Control Practices for Dentistry, 1993." MMWR 1993; 42/No. RR-8: 1-11.

B. Physical Description of the Handpiece or Attachment

Copies of labeling material cannot be substituted for the information requested in this section.

1. Detailed, keyed drawings and/or photographs; overall dimensions as well as dimensions of the head and the visibility angle should be provided (See references 5 and 8). Provide a keyed list of parts of the handpiece.

2. Material composition of all components. Identify the materials that comprise each part on the keyed list in item 1. Include specifications or standards to which the materials comply.

3. Minimum and maximum shank length to be used

4. Type of bur shank to be used. Identify with common terminology and relevant standards.

5. Type of chuck

6. Features, including air/water spray, fiberoptic coupling, built-in lamp,

swivel coupling, swivel head

7. Installation requirements; interfacing devices. Identify the interfacing mechanism between the components of the device and between the device and the dental unit in generic terms or with a reference to standards.

   a. Dimensional requirements. Provide the dimensions or identify the standard which the interfacing device meets (see ref 2).

   b. Physical requirements, e.g., air pressure range in psi, requirements for electrical control unit compatibility.

   c. Electromagnetic Compatibility, e.g., immunity to AC line noise, auto shut-off feature, electrical filters.

8. Describe cleaners and lubricants required.

9. Identify and briefly describe accessories or attachments to be marketed or used with the device; use ADA specifications or ISO standards where applicable.

   State which components are included with the device, which are available as an option, and which conform to industry standards with respect to the connections.

C. Predicate Device(s)

1. Identify a legally marketed device to which substantial equivalence is claimed.

2. Provide labeling for the device to which equivalence is claimed, if possible.

3. Compare and contrast the designs and specifications.
   This information should be provided in tabular form comparing the properties of the handpiece to those of the predicate device(s). It can include results of published or unpublished studies carried out on the device.

D. Performance Tests

Identify the applicable ISO standards to which the device conforms. If any portion of the applicable performance criteria is not met, explain why this does

not adversely affect its safety or effectiveness. The following additional performance criteria should be provided:

1. Maximum air pressure at which the handpiece and hose connections will remain intact and the free running handpiece will retain a bur/test mandrel. The hose connections should remain intact when the air pressure is no less than 150% of normal operating air pressure.

2. Surgical handpieces with separate irrigant delivery system. The following refer to the irrigation system that will accompany the handpiece or the properties of an adequate system for use with the device.

    a. Irrigant flow rate

    b. Information to demonstrate that the irrigant provide adequate irrigation at the surgical site

    c. If labeling states that the system is designed to minimize cross-contamination, provide information adequate to substantiate this claim. Such information should include with engineering drawings, photographs, description of operation, published or unpublished studies and comparison to other legally marketed systems.

3. Light output, if integral to the handpiece

    a. At least 10,000 lux (1 lux = 7.96×10^{-2} candela)

    b. Effect of repeated sterilization and use cycles on color spectrum.

    c. Location and distribution

4. Turbine air release, with respect to surgical use claim

    For restorative handpieces also intended for use in oral surgery, the issue of air release at or near the handpiece head must be addressed. Air release must be redirected away from the head of the handpiece.

5. Additional performance criteria for handpieces with push-button locking chuck (high and low speed)

    In the confined field in which operative dentistry is performed, inadvertent application of force to the rear of the handpiece head is

routine. If the push-button is depressed and the release mechanism contacts internal rotating parts, the resulting friction has the potential of posing a burn hazard.

To minimize this hazard, a minimum axial load of 3.34 N (12 oz.) on the push-button should be required before the release mechanism contacts rotating parts.

If the device is to be marketed with a lower push-button force, the applicant should show that the burn hazard is no greater than is posed by a legally marketed handpiece. This should be accomplished by comparing designs, dimensions of heads and buttons, force required to develop friction in the heads during operation, and the temperature achieved during identical operating conditions of air pressure, r.p.m., lateral and axial loads, and ambient temperature.

6. Impact resistance for single use handpiece (drop test)

   a. The handpiece should be disconnected from its hose and dropped, head down, onto a hard surface from a height of three feet. Single use contra-angles should be attached to a suitable micromotor before being dropped in the same manner. At least ten randomly selected samples should be dropped. Following the impact, all of the samples should withstand the air pressure test cited in item II.D.1.

   b. If impact resistance is not demonstrated, labeling should advise immediate disposable of a dropped handpiece (See item II.F.3.k.).

E. Sterilization Validation

1. The manufacturer must confirm the sterilizability of the handpiece, using a method based on a heating process capable of sterilizing the device, including its most inaccessible surfaces to a sterility assurance level (SAL) for the device at the 10^{-6} level. Common methods used to sterilize devices intended for reuse include steam under pressure, dry heat and dry heat with chemical vapor. Gamma radiation and use of ethylene oxide are acceptable methods for sterilization of devices that are sold in sterile form and are intended for single use only. Data on the method used to validate the sterilization cycle must be maintained on file by the manufacturer. This recommendation applies whether sterilization of the device prior to use is carried out by the applicant

(manufacturer/distributor) or the user. Instructions to the user for sterilization (See item II.F.3.g.4) must match the conditions of the validation testing, including use of wrapping, time, temperature, type of sterilizer and permissible load.

The validation protocol should take into consideration the following:

a. Inoculation method

b. Organism name. The test organism selected will depend on the sterilization method used, namely, Bacillus stearothermophilus (ATCC 7953) for steam and Bacillus subtilis var. niger (ATCC 9372 or 19659) for dry heat. For devices not intended for reuse, and sterilized prior to distribution by gamma radiation or ethylene oxide, appropriate test organisms must be used.

c. Location of organisms: Inoculation sites should include unsealed internal locations which offer the most difficult access for the sterilant. A diagram of the device showing the exact location of the inoculation sites must be provided.

d. Sterilization method and parameters. The cycle overkill method for validation is encouraged: if a 6-log reduction in the number of challenge organisms is obtained with one-half the cycle exposure time, then a full cycle, as described in the instructions, would cause a 12-log reduction or a 10^{-6} probability of microbial survival (10^{-6} SAL).

e. Samples per run; number of runs; a minimum of 3 runs; 3 handpieces/run should be tested. Handpieces selected for sterilization validation testing should be randomly selected from production.

f. Wrapping

(1). Package description, if the device is provided sterile (See references 3 and 4)

(2). Description of wrapping, if used

2. The manufacturer must have on file data to support the number of reprocessing cycles.

a. Maintain a record of the data that show that the handpiece can

withstand the number of reprocessing cycles claimed in the labeling (See item II.F.3.g.5) with less than a 10% decrease in the performance characteristics listed in section II.L. The test protocol must include application of appropriate loading between reprocessing cycles. Upon completion of testing, performance characteristics should in no case be below the minimum described in section II.D.

In order to minimize the time needed to obtain reprocessing data, accelerated wear testing is acceptable. For example, 30 cleaning and sterilization cycles, followed by handpiece use equivalent to 30 use cycles, may be utilized in lieu of 30 use/reprocessing cycles. This office recognizes the difficulty of quantifying the time, r.p.m., and load parameters that are typical in a single dental appointment.

b. Maintain evidence of material/process compatibility (see ref 2).

F. Labeling

1. Proprietary Name. Use of a proprietary (trade) name that implies an infection control advantage is unacceptable.

2. Device markings and package labels

   a. FDA recommends that markings denoting the following information be placed on each device:

      (1) Sterilization method

      (2) Maximum sterilization temperature

      (3) Maximum number of use/reprocessing cycles before disposal or repair required (See item II.E.2.a)

   b. Handpieces or handpiece systems that contain electrical parts and are intended for use in ordinary locations should bear a prominent marking which warns against use of the device in the presence of flammable anesthetics (Specific wording and symbols explained in reference 6, UL 544, paragraph 52.1).

3. Instruction Manual

   a. Intended use(s)

b. Contraindicated use(s)

c. Name and address of manufacturer

d. Type and model designation

e. Installation/connection instructions. Use generic names of interfacing devices, reference to standards for size, configuration, pressure, flow rate and voltage.

f. Operating instructions

g. Sterilization instructions (Sterilization validation requirements for the submission are found in section II. E.)

(1). Labeling indicating the sterilization status of the handpiece as supplied, e.g., sterile (single use); non-sterile, but sterilization required prior to use/reuse

(2). Labeling for handpiece with air and cooling water lines. Instruct the user to run the handpiece for a minimum of 20-30 seconds to flush the water and air lines after use on each patient prior to disconnecting for reprocessing (See reference 9

(3). Labeling indicating that the FDA recommends that a reusable handpiece be heat sterilized between patients.

(4). A detailed description of the method for decontamination and sterilization should be provided. This is to include the proper method of preparing the handpiece for sterilization with detergents and/or enzymes and the necessity, if any, for disassembly and additional lubrication between sterilization cycles. The type of cleaner/lubricant is to be identified. The recommended resterilization parameters must be identical to those used in the sterilization validation study (section II.E). An exception is that the instructions should recommend twice the half-cycle exposure time that was used for sterilization validation (overkill method). Advice to follow recommendations of the sterilizer manufacturer is inadequate.

(5) State the number of use/reprocessing cycles that the

handpiece can withstand before disposal or repair is required.

(6) If the device includes a low-speed micromotor, which is not placed in direct intraoral patient contact, labeling may state that this component may be reprocessed by performing step (2), followed by disinfection and placement of a disposable sleeve, in lieu of sterilization. The specific sleeves must be provided, sold, and/or recommended by the applicant.

h. Maintenance tasks

i. Maintenance schedule

j. Repair instructions and/or reference to responsibility

k. Warnings, hazards, and precautions, including the warning for dropped handpieces, if applicable (See item II.D.6)

l. Source of further information

For additional information, contact:

Food and Drug Administration
Center for Devices and Radiological Health
Dental Devices Branch
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Rockville, MD 20850
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