

ADA American
Dental
Association®

Acceptance Program
Guidelines

Oral Irrigating Devices

Council on Scientific Affairs

Oral Irrigating Devices

Scope: These guidelines apply to both electrically powered and water pressure powered oral irrigating devices.

I. SUBMISSION DIRECTIONS

1. General Information

A Submissions are to be sent to the Council Office:

**Director, Product Evaluations
American Dental Association
Council on Scientific Affairs
211 East Chicago Avenue
Chicago, Illinois 60611 - 2678**

B Submissions are to be sent in triplicate along with a market sample of each product under evaluation and packaged as marketed. One single-sided copy for duplicating purposes shall be provided. The Council agrees to return the product sample within six months if requested. If possible the submission should be less than 200 pages exclusive of appendices.

C A manufacturer is advised that the review process is complex. Typically, notification of Council action may be expected 90 to 150 days from the receipt of a complete submission by the Council. More time may be required if additional information or clarification is needed from the manufacturer.

D When a product is classified as "accepted" the classification is for 3 years. Renewal of the classification will be considered by the Council upon request by the manufacturer.

E Classification of a product under the Acceptance Program is subject to the conditions stated in the Agreement Governing Use of ADA Seal of Acceptance.

2. Arrangement of a Submission

A The submission is to be divided into sections and arranged in order as indicated in part II. Sections to be identified by tabs are designated by *.

II. INFORMATION TO BE SUBMITTED

1. Cover Page

A Name of company

B Product name

*2. Table of Contents

*3. Company Information

A Name of company (to be used in listing)

B Address (to be used in listing)

C Phone Number (to be used in listing)

D Fax Number

E Names of owners, officers and other individuals authorized to furnish information to the Council and represent the firm in dealing with the Council.

F Names and qualifications of scientific personnel responsible for formulation and testing of the product in its manufacturing process.

*4. Summary of submission.

Comprehensive summary of all information on safety and effectiveness of the oral irrigating device.

*5. Product Information

A Name of product (to be used in listing)

B Claims of efficacy and safety

(i) Claims for the device must be appropriate based on the population used in any clinical studies.

(ii) Oral irrigating devices which meet these guidelines will be able to make claims such as "reduces gingivitis" or "helps prevent gingivitis". Any claims beyond this will require additional laboratory and/or clinical studies.

(iii) Advertisements must avoid disparagement of other oral irrigating devices or other oral hygiene products.

C Patent title(s) and patent number(s) relating to the product.

D Product description

(i) List the materials used in the construction of the product.

(ii) Principles of design.

E Labeling

F Packaging

G Promotional materials

***6. Quality Control Procedures for the Manufacturing of the product.**

***7. Safety Data**

A As evidence of technical safety, an oral irrigator of the powered type must have been submitted for examination by and meet the requirements of an appropriate testing laboratory such as listing by Underwriters' Laboratories, Inc.

B A means for adjusting water pressure must be provided for oral irrigators of the powered type.

C Those devices dependent upon water line pressure and not powered must be equipped with a safety mechanism or valve for release from the water line at high pressure.

D Adequate evidence must be available from clinical investigations to show that unsupervised use of the device will not be harmful to oral hard or soft tissues, dental restorations or orthodontic appliances (see clinical protocol guidelines).

***8. Efficacy data -- clinical data to show effectiveness.**

Adequate evidence must be provided from at least one clinical investigation (see clinical protocol guidelines) of at least 25 subjects per test group to show that the product can be employed under unsupervised conditions by the average layman to provide not only a high degree of oral cleanliness but demonstrate a 20% reduction in gingivitis over standard oral hygiene procedures. Populations selected for the studies must be representative of individuals for whom the product is intended, which, in most cases, would be individuals with mild to moderate gingivitis. Trials must report all treatment groups.

***9. Comprehensive bibliography**

***10. Copies of most significant articles.**

***11. Appendices**

Evaluation forms, individual case histories, detailed description of test evaluation methods and any other defined areas should be included.

III. REQUIREMENTS (PERFORMANCE CRITERIA) FOR CLASSIFICATION OF "ACCEPTED":

The oral irrigating device must meet all of the safety, efficacy and claims of efficacy requirements as specified above."

IV. STATEMENT TO BE USED FOR PRODUCTS CLASSIFIED UNDER THESE GUIDELINES:

"The ADA Council on Scientific Affairs' Acceptance of (product name) is based on its finding that the product is effective for reducing or preventing gingivitis, when used as directed."

CLINICAL PROTOCOL GUIDELINES

The following guidelines are given for the design and conduct of clinical studies using oral irrigating devices to provide evidence of safety and effectiveness in reducing gingivitis. Additional information concerning clinical trials and clinical trial reporting can be obtained from the ADA Acceptance Program Guidelines for Clinical Trial Protocols (see References). Manufacturers are encouraged to submit their clinical protocols to the Council for review prior to the start of clinical studies.

Sample Size: Sufficient subjects shall be enrolled in the study so that a statistically significant difference between the active and control groups can be demonstrated. Subjects will be randomly assigned a commercially available ADA Accepted toothbrush and dental floss (if applicable) and will be randomly assigned the test product and the same ADA Accepted toothbrush and floss (if applicable). Each subject will have a complete oral cavity examination to determine eligibility for the study. In general, subjects should be adults of normal health with mouths free from major hard or soft tissue lesions. At the baseline visit, patients will be given written and verbal oral hygiene instructions consistent with proposed claims for the product, e.g. if claims address effectiveness compared to brushing and flossing, then both brushing and flossing instructions must be given.

Study Duration: The study will be conducted for at least 30 days. Clinical measurements will be taken at baseline (prior to the study), at 15 days and at the end of the study (30 days).

Safety Assessments: Safety assessments will be made at each measurement period. Areas to be examined will be the tongue, hard and soft palate, gingivae, mucobuccal folds, the inner surface of the cheeks and sublingual space areas. Any effects on hard tissue and/or dental restorations will be noted.

Gingivitis Assessments: At each visit, scoring of gingival inflammation (gingivitis) will be done at all study sites. The Gingival Index of Löe & Silness is an acceptable method. If a different index is used, its rationale should be provided. Additional assessments of interproximal health such as bleeding on probing are recommended. Assessment of gingivitis should be done prior to the scoring of plaque to avoid masking the gingival inflammation with plaque-disclosing agents. Justification for the particular gingival index used must be provided. Full mouth evaluations should be performed. Evaluations will include measurements at the papillae area of the gingival margin.

Clinical Procedure: Between the baseline and 30 day examination, each subject will be instructed to clean his/her teeth daily, using only the assigned products provided. Unused products should be returned at the end of the study for examination to determine compliance.

Statistical Analysis: Mean group scores for gingival indices on all surfaces will be compared at baseline, 15 days, and 30 days with either a parametric or non-parametric test for matched pairs. If more than two groups are being evaluated appropriate multiple comparison tests should be used. Where appropriate, a non-parametric test will be used to assess the safety evaluation data (normal vs. abnormal).

Notes:

1. It is desirable to provide a measure of intra- and inter-evaluator variance.
2. An attempt should be made to assess the level of compliance of the subjects in the study. Examination of the toothbrush condition at the conclusion of the study is one method of attempting this assessment.

References

1. ADA Council on Scientific Affairs. Acceptance Program Guidelines: Clinical Trial Protocols. Chicago: American Dental Association, 2007.

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advocate for oral health

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