

Acceptance Program Requirements



Powered Interdental Cleaners or Oral Irrigators



Acceptance Program Requirements

This document outlines specific category requirements. Please also refer to the General Guidelines for Participation in the ADA Seal of Acceptance Program.

Category:	Powered Interdental Cleaners or Oral Irrigators
Purpose:	The Acceptance Program applies to over-the-counter dental products for which safety and efficacy has been established by laboratory and/or clinical evaluations where appropriate. Accordingly, the purpose of these requirements is to provide a structure upon which powered devices for interdental cleaning and/or oral irrigating can be considered for ADA Acceptance.
Scope:	These requirements apply to both electrically powered and water pressure powered interdental cleaning and/or oral irrigating devices meant for reduction of interproximal plaque and gingivitis and/or whole mouth plaque and gingivitis.
Notice Regarding Submission of Copyrighted Materials:	To make the review of submissions to the ADA Acceptance Program as efficient as possible, the Council on Scientific Affairs provides copies of submitted materials to Council members and consultant reviewers, and also posts submitted materials to an area of the ADA's web site the access to which is restricted to Council members and staff.

By making a submission, you are representing and warranting to the Council on Scientific Affairs and the ADA that you have obtained sufficient permission(s) from the copyright owner(s) of any copyrighted material included with your submission to allow for the publication and distribution of that material by the ADA as described above, and agree to indemnify and hold ADA harmless from any and all claims arising from such publication or distribution.

Questions can be directed to adaseal@ada.org.

1. **SEAL STATEMENT**

The following statement applies to products approved under the below-listed criteria:

“The ADA Council on Scientific Affairs’ Acceptance of (Product Name) is based on its finding that the product is safe and has shown efficacy in removing plaque (between teeth) and helping to prevent or reduce gingivitis (between teeth) when used as directed.”

Format for product packaging:

- Helps remove plaque (between teeth)
- Helps prevent or reduce gingivitis (between teeth)

2. **SUBMISSION DIRECTIONS**

- A. Submissions are to be sent in electronic format (email) to adaseal@ada.org. Additional instructions will be provided regarding shipment of necessary samples.
- B. The submission fee is a one-time, non-refundable fee and is required before review begins. Maintenance fees are billed to the company in January of every year.
- C. The review timeline for new submissions is typically 4-6 weeks after all materials have been received. The decision to award the ADA Seal to a new product is made by the Council on Scientific Affairs. Family submissions may take anywhere from 2-4 weeks to review. Eligibility criteria for Family Submissions are outlined in the Guidelines for Participation in the ADA Seal of Acceptance Program.

Note: This is an estimated timeline. Extended review time may be required if additional information or clarification is needed from the manufacturer.

- D. When a product is classified as “Accepted” and is awarded the ADA Seal of Acceptance, the Acceptance period is five years. Manufacturers will be contacted approximately six months before the expiration of the current Acceptance period to complete the requirements for the next five-year Acceptance period.
- 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.
- F. Guidelines for the design and conduct of clinical studies are provided in Appendix I. Manufacturers interested in seeking the ADA Seal of Acceptance are encouraged to submit their clinical protocols to the Council for review prior to the start of clinical studies.

3. **SUBMISSION MATERIALS**

All submissions must include the following information based on product type and comply with the ‘General Criteria for Acceptance’ described in the Guidelines for Participation in the ADA Seal of Acceptance Program.

A. Product Information

- i. Name of product(s)
- ii. Name of company

iii. FDA Documentation

- a) FDA registration and product listing must be provided.
- b) Evidence of FDA approval to market, if applicable (e.g., 510 (k) letter, pre-market approval, NDA/Evidence of FDA registration).

iv. Product Claims

- a) Products approved under these category requirements will receive the following Seal bullet claim: helps remove plaque (between teeth); helps prevent or reduce gingivitis (between teeth). Data required to substantiate efficacy towards the Seal bullet claim is explained in Section C below. ***Please provide a list of all additional safety and efficacy claims beyond the Seal bullet claim. These claims should follow the ADA Brand Standards and must undergo review and approval by the Council on Scientific Affairs before they can be included on product packaging.*** Substantiation for any health benefit claims, outside of the Seal bullet claims, must be provided through clinical and/or laboratory data specific to the product and is not addressed in Section C below. Whether clinical or laboratory data is required depends on the nature of the claim. For any questions regarding claim substantiation, please contact the ADA Seal Program.
- b) Disqualifying Claims: The Council believes that because plaque is the etiologic agent for gingivitis and other oral disease, the only Accepted products that will be allowed to make plaque control claims will be those that can demonstrate a significant effect against gingivitis. If a product can only demonstrate a significant plaque reduction without a concomitant significant reduction in gingivitis, it will not be eligible for Acceptance.

v. Product Specifications

- a) Chemical composition or components of the product and purpose of the various ingredients. To facilitate review, submitting the chemical composition, concentration, and purpose in tabular form is recommended.
- b) Material Safety Data Sheet (MSDS): for different body parts (such as nozzle, reservoir, handles, filaments, infusions), and case (if any).
- c) Design of the product: dimensions and shapes of all components, different functional modes, filament types, etc.

vi. Product Manufacturing

- a) Describe or list the quality procedures for manufacturing or testing of the product which demonstrate compliance with Good Manufacturing Practices.
- b) Certification of Good Manufacturing Practices can also be provided.

vii. Product Instructions

- a) Include detailed instructions for product use.
- b) Include indications and contraindications for use, warnings, etc.

viii. Product Labeling/Packaging

- a) All labeling/packaging should follow the ADA Brand Standards and must be approved by the Council on Scientific Affairs before use. Companies may submit draft copy for approval. See iv. Product Claims above.

ix. Product Samples

- a) Submission requires three samples, one from three different production lots for analysis by the ADA Laboratories.

B. Safety Data

- i. Evidence must be provided that the components of the product are safe for use in the oral cavity (as outlined under 3.A.v. Product Specifications). When appropriate, standard toxicological, mutagenic, and/or carcinogenic testing may be required. Compliance with applicable FDA standards should be provided (where appropriate).
- ii. As evidence of technical safety, a powered interdental cleaner or oral irrigator must meet the requirements of an appropriate testing laboratory such as those listed by Underwriters' Laboratories, Inc. **Safety testing certifications – UL, ETL, CSA, or other laboratory certification or approval must be provided.**
- iii. A means for adjusting water pressure must be provided. For oral irrigators, the water pressure generated by each mode (if applicable) should be documented and justification of efficacy should be provided if the water pressure exceeds 90 psi.
- iv. Those devices dependent upon water line pressure and not electrically powered must be equipped with a safety mechanism or valve for release from the water line at high pressure.
- v. If the device is marketed to be used with any solution other than water, additional safety testing and/or clinical trials will be required.
- vi. Where applicable (such as powered interdental brush and floss), the product should comply with the requirements of ISO Standard No. 28158 Dentistry – Integrated Dental Floss and Handles or ISO Standard No. 16409 and ANSI ADA Standard No. 125 for Manual Interdental Brushes.

C. Efficacy Data

- i. Supply one copy of all available physical and chemical property information developed in laboratory studies or similar materials that might be predictive of clinical use/behavior.
- ii. Clinical study data must be supplied to demonstrate product efficacy as follows:
- a) If device does not differ significantly in design or function from these currently in the ADA Seal of Acceptance Program, one clinical efficacy study is required. Evidence of similarity with the Accepted product must be submitted for consideration.
- b) If device differs in design or functionality from other interdental cleaners/irrigators currently in the ADA Seal of Acceptance Program, two independent clinical studies are required.

- iii. Clinical studies generated in support of a Seal application should follow study specifications found in the Appendix.

D. Supporting Literature: Copies of the most significant articles or supporting literature demonstrating safety or efficacy of the product should be provided, where applicable.

4. REFERENCES

The following references were used in the development of these requirements and can be consulted for a more detailed discussion:

- ISO 28158, Dentistry - Integrated Dental Floss and Handles, 2018
- ISO 16409, Dentistry – Oral Hygiene Products – Manual Interdental Brushes, 2016.
- ANSI/ADA Standard No. 125 Manual Interdental Brushes, 2018.
- ADA Brand Standards: https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/seal/ada_seal_brand_standards_nov2024.pdf

Appendix

Clinical Protocol Guidelines for Powered Interdental Cleaners or Oral Irrigators

The following guidelines are provided for the design and conduct of clinical studies to generate evidence for the evaluation of safety and efficacy of powered interdental cleaning or oral irrigating devices. These guidelines attempt to define minimal requirements necessary to provide evidence of efficacy and safety in reducing gingivitis and removing plaque. Manufacturers are encouraged to submit their clinical protocols to the Council for review prior to the start of clinical studies. The information indicated below is applicable to each independent clinical study.

Study design: Clinical trials should be randomized whenever possible, with participants allocated to treatments through a randomization process. Studies should be blind regarding participants, examiners and data analysts; when blinding is not possible, a justification must be provided. IRB approval is required for all studies involving human subjects. The frequency of use of the product should be representative of actual use of the product in practice; and the user should be instructed in the proper use of the product but not necessarily supervised. Studies must report all treatment groups, and an attempt should be made to assess the level of compliance of the subjects in the study. Studies should be conducted for at least a 30-day period, with measurements taken at baseline, 15 days (optional) and 30 days.

Number of studies: If multiple studies are submitted, they should be conducted at a different site and include a separate participant pool. Studies are expected to be independent, and free from direct control from the manufacturers. Studies are expected to adhere to the CONSORT guideline, and the checklist should be completed and uploaded with the submission.

Sample size: The protocol should describe how sample size was determined, including all assumptions supporting the calculation and clearly defining the primary and secondary outcome variable(s) for which the study is being powered. A power of at least 80%, at an alpha error of 5%, is expected for variables leading to a Seal claim.

Eligibility criteria: Trial participants should be representative of the population for which the product is intended. Inclusion and exclusion criteria for participant's enrollment should be clearly described. Each subject will have a complete oral examination to determine eligibility for the study, with both genders and representative age groups included according to intended use. In general, subjects should be adults of normal health with mouths free from major hard or soft tissue lesions. Entry criteria should include patients with mild to moderate gingivitis and exclude those with aggressive, necrotizing, or other uncommon periodontal disease states.

Test product and comparator: The test product should be compared with standard of care products/methods as defined by the ADA. Clear determination is to be made about the goal of the study to show superiority, equivalence or non-inferiority.

Clinical procedures: The phases of the study (lead-in, test, wash-out, when applicable) should be clearly described, preferably using a diagram. The instructions given to participants regarding any study-specific procedures should be clearly described. The duration of the study, and when assessments will be performed, must be clearly described. For studies involving evaluators, their number and calibration methods should be provided, as well as intra/inter examiner agreement data. All clinical examinations will be performed by an investigator who has no knowledge of the oral hygiene devices used by the subjects. It is desirable to provide a measure of intra- and inter-evaluator variance. Between baseline and 30 days examination, each subject will be instructed to clean his/her teeth daily using the control toothbrush and a fluoride dentifrice with (treatment group) or without (control group) the additional use of the powered interdental cleaning or oral irrigating device. Subjects must refrain from the use of any non-study related dental products as well as from any elective dental procedures until the study is complete.

Assessments for efficacy: Variables assessing efficacy should be clearly described and allow for a comparison between the test product and the comparator. Only products that significantly reduce both plaque and gingivitis may claim plaque control. If a product demonstrates significant plaque reduction without a concomitant significant reduction in gingivitis, it is not eligible for Acceptance.

Gingivitis Assessments: Methods should be selected that measure gingivitis using both subjective and objective criteria. The comprehensive Löe & Silness gingival index which incorporates both bleeding and visual appearance can be used. Alternatively, the visually based Modified Gingival Index can be used along with an index of gingival bleeding, such as the Eastman Interdental Bleeding Index. Full mouth evaluations including 6 sites per tooth (mesio-buccal, disto-buccal and mesio-lingual, lingual, disto-lingual) on a minimum of 20 teeth should be performed for studies aimed at evaluating whole mouth gingivitis. For claims focused on interproximal gingivitis reduction, 4 interproximal sites per tooth (mesio-buccal, disto-buccal and mesio-lingual, disto-lingual) on a minimum of 20 teeth should be evaluated.

Plaque Assessments: Plaque will be scored before and after brushing at each examination using the Turesky modified Quigley-Hein Index, or another appropriate and validated index. Full mouth plaque evaluations should be performed.

Assessments for safety: Variables assessing safety should be clearly described and allow for a comparison between the test product and the comparator. Safety assessments will be made at each measurement period on oral soft and hard tissues and restorations. 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 should be reported and analyzed (normal vs abnormal) by an acceptable non-parametric test. In particular the cervical root area will be carefully examined.

Statistical analysis: Depending on the type of study (superiority, equivalence, non-inferiority), the statistical analysis plan should be described allowing for a comparison between the test product and the comparator, for all study variables, considering the predetermined power and significance level.

Mean group whole mouth scores for plaque and gingivitis on all surfaces will be compared at baseline, 30 days, and at an (optional) intermediate period with appropriate statistical tests. If more than two groups are being evaluated appropriate multiple comparison tests should be used. The basis for statistical sizing must be provided in the protocol. Information to be provided includes expected examiner variance, the targeted alpha and beta values, the estimated drop-out rate, and the targeted treatment differences.

A pooled average of at least 10% (using the Modified Gingival Index) or 15% (using the Löe and Silness Gingival Index) compared to baseline is required to demonstrate a reduction in gingivitis; the confidence interval must be provided. Plaque measurements shall demonstrate that quantitative plaque reductions are statistically significantly different from the control group. Where appropriate, a non-parametric test will be used to assess the 90-day safety evaluation data (normal vs abnormal).

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