



m2546n

APR 23 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

VIA FACSIMILE

Earl O. Bergersen, Ph.D.
President
Ortho-Tain, Incorporated
950 Green Bay Road
Winnetka, Illinois 60093

Re: Nite Guide® Dental
Appliance; "G" and "C"
Series, K931615

Dear Dr. Bergersen:

The Food and Drug Administration (FDA) has reviewed promotional materials for the Nite-Guide® Dental Appliance and "G" and "C" Series (Nite-Guide®). These products are manufactured by Ortho-Tain, Incorporated (Ortho-Tain) and are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Nite-Guide® appliance has been cleared under section 510(k) of the Act and is a preformed dental appliance designed for deciduous dentitions to allow ideal eruptive guidance of the mandibular and maxillary permanent incisors. The "G" series is used in the same way after the eruption of the first permanent molars. The "C" Series is applicable where diagnostic criteria of malocclusion and stage of dental development are met. Specifically, the following intended uses are permitted:

- Any potentially deep permanent overbite (over 3 mm) developing from a deciduous overbite exceeding 1.25 mm (worn only while sleeping);
- Any overjet up to 4 mm (worn only while sleeping);
- Potential crowding of the permanent incisors where the deciduous arch is predicted to be up to 7 mm short of adequate spaces (worn only while sleeping);
- Correction of some open bites where thumb-sucking habits have been corrected and where no anterior tongue thrust exists (worn only while sleeping);
- Correction of some cross-bites in the posterior area that is not caused by a mandibular lateral displacement;

-Correction of most overjets exceeding 4 mm (worn only while sleeping plus 1 to 2 hours of daytime active exercise).

We have reviewed your web site at the internet address: <http://www.Ortho-Tain.com> as well as an Ortho-Tain booklet to parents titled, Orthodontic Breakthrough...Nite-Guide®. Straightens Teeth While Your Child Sleeps. These pieces make claims for the Nite-Guide® which have not been cleared by the agency i.e., correction and/or treatment of TMJ problems, treatment of gummy smiles, and the correction of Class I, end to end, and Class II molar relation malocclusions (worn only while sleeping). Representative examples of these claims are as follows:

-“A child may be a candidate for this treatment if he/she has: crowded and rotated teeth, overjet, gummy smile...” (Orthodontic Breakthrough) (Underlining added)

-“... The Nite-Guide® Appliance can guide adult front teeth into their proper positions and eliminate crowding, rotations, overjet (buck teeth), gummy smiles, open bites, and many TMJ (jaw joint) problems;” (Orthodontic Breakthrough) (Underlining added)

-“The appliance can eliminate overjet (buck teeth), crowding, overbite (where the upper front teeth cover most or all of the lower front teeth when the child closes his/her jaws) and can correct many TMJ (jaw-joint) problems.” (Ortho-Tain web site) (Underlining added)

-“Correction of Class I (normal jaw relation in profile), end to end, and Class II malocclusions (where the lower jaw is smaller in relation to the upper jaw).” (Ortho-Tain web site) (Underlining added)

Many other sections of both the web site and the promotional brochure contain references to the above (uncleared) intended uses, but they are too numerous to include here.

In a March 15, 1995 letter from Mr. John W. Cornell, Hill, Steadman & Simpson, your legal representative, Ortho-Tain made a commitment to remove all claims related to the treatment of TMJ and to the elimination of gummy smiles from its labeling and promotional materials. Yet, these claims are apparently being perpetuated by Ortho-Tain. Furthermore, your clearance letter of April 14, 1995, specifically stated that your substantial equivalence determination did not include the treatment of TMJ problems, treatment of gummy smiles, or references to correction of crowding greater than 7 mm.

The Dental Officer's (Gregory Singleton, D.D.S.) memorandum to the file dated September 20, 1993, indicates that the controlled clinical trial results which you submitted in the Journal of Clinical Pediatric Dentistry, Volume 14, No. 4, 1990, do not support Nite-Guide®'s claims for treating TMJ problems, gummy smiles, or for correcting Class I, end to end, and Class II malocclusions. Such claims represent a major

modification in the intended use of the device as described under 21 CFR 807.81(a)(3)(ii), and require the submission of a new 510(k).

Continued promotion of the Nite-Guide® for claims for the treatment of TMJ problems, gummy smiles, or for Class I, end to end, and Class II malocclusions, causes the Nite-Guide® to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Nite-Guide® is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modifications in the intended use(s) of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

The 510(k) record also shows that you agreed to change the word “most” to “some” in the correction of open bites, and in the correction of cross bites; and to change the word “any” to “most” when referencing the correction of overjets exceeding 4 mm. It appears that the description of the Nite-Guide® “C” Series on your web site continues to have the older version of the labeling including the words “any,” “many,” and “most” in opposition to what Ortho-Tain had previously agreed to.

Ortho-Tain should ensure that all of its labeling and promotional materials for the Nite-Guide® device are in compliance with the requirements set forth by the Office of Device Evaluation (ODE) and cleared in your 510(k) submission.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Nite-Guide® device. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

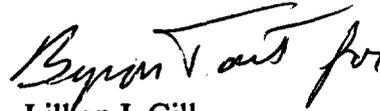
Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Page 4 – Mr. Earl O. Bergersen

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Chicago District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Chicago District Office (HFR-MW100), 300 South Riverside Plaza, 5th Floor, Suite 550 South, Chicago, Illinois 60606.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian J. Gill" with a stylized flourish at the end.

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health