



DEPARTMENT OF HEALTH & HUMAN SERVICES

NFI-85

Public Health Service

D1223B

FEB 26 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

Michael D. Sobo, President
SAS Group, Inc.
220 White Plains Road
Tarrytown, New York 10591

Re: PlusTron Ion Toothbrush System

Dear Mr. Sobo:

This is a follow-up to your letter dated December 4, 1996, which was in response to our November 5, 1996, letter to James Hastings, SAS Group, Inc., concerning your PlusTron Ion Toothbrush System, intended to repel plaque with ion cleansing. This product is considered a device as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

We have reviewed the information you submitted in the referenced December 4 letter. The response provided your rationale for commercially distributing the PlusTron Ion Toothbrush System without the submission of a premarket notification 510(k). However, the product described in your labeling and advertising differs in sufficient respects from the product as described in your argument; therefore, we herewith inform you that the product you are marketing is not excluded from the premarket notification requirements [510(k)], and Good Manufacturing Practice requirements, as described in Title 21 Code of Federal Regulations, part 820.

Initially, you question whether the PlusTron Toothbrush is a device; however, you then conclude that the PlusTron is exempt from premarket notification because it falls within the device classification regulation contained in Title 21 of the Code of Federal Regulations 872.6855 (21 CFR 872.6855). For your information, the device classified as a manual toothbrush is exempt from premarket notification per section 510(k) of the Federal Food, Drug, and Cosmetic Act; however, your labeling makes such claims as "...IONIC CLEANSING ACTION...", and "...MORE THAN A TOOTHBRUSH...". These claims go beyond those for devices meeting the classification for a manual toothbrush (21 CFR 872.6855), and require the submission of a premarket notification which must be found substantially equivalent by the FDA prior to commercial distribution.

Our records indicate that your firm has failed to submit a premarket notification [510(k)] for this device. Failure to submit a 510(k) at least 90 days prior to offering this device for sale in interstate commerce results in this device being considered misbranded within the meaning of section 502(o) of the Act. Further, because this device has not yet been found substantially equivalent to a predicate device through the review of a 510(k) submission, this device is also adulterated within the meaning of section 501(f)(1)(B) of the Act, in that it has been offered for

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sale in interstate commerce for the first time after May 28, 1976, thereby statutorily classifying it as a Class III device, and it fails to have, as required under section 515(a), an approved application for premarket approval (PMA), and it is not exempt from such requirement under an Investigational Device Exemption (IDE) [section 520(g)].

You should take prompt action to correct these violations. Continued distribution of the device may result in regulatory action by the Food and Drug Administration without further notice. These actions include, but are not limited to, injunction, seizure, and/or civil penalties.

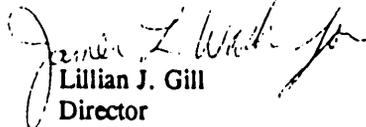
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please reply to this office, in writing, within 15 days of the receipt of this letter, describing the specific steps you have taken to correct the noted violations, including steps taken to prevent the recurrence of similar violations. If the violations cannot be corrected within 15 days, explain the reason and provide a time line specifying the time within which corrective action will be completed.

A copy of this letter is being sent to the responsible FDA District Office. Please send a copy of your response to the District Director, New York District, Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232. We request that any action being taken to remove this product from the market be reported to the above mentioned District Office.

Your response to this letter should be sent to the attention of Mr. Jack Hessman, Dental, ENT and Ophthalmic Devices Branch, HFZ-331, at the letterhead address.

Sincerely yours,



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

cc: James Hastings, SAS Group, Inc.