



DEPARTMENT OF HEALTH & HUMAN SERVICES

M 968 N

Public Health Service

1 30-

01/1/97
CJW

JUN - 3 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Hiroji Sekiguchi
Vice President/Dental Operations
NSK America Corporation
700-B Cooper Court
Schaumburg, Illinois 60173

Re: NSK High Speed Air
Turbine Dental Handpiece
with Clean Head™ System,
K962543

Dear Mr. Sekiguchi:

The Food and Drug Administration (FDA) has reviewed your April 24, 1997 response to our letter dated March 31, 1997. We find your response unacceptable (see below).

Your response included 7 international journal reprints and a videotape prepared by Nakanishi Dental Manufacturing Company titled, "Infection Control. Clean Head System." Additionally, we have also reviewed your revised promotional piece titled, "Help Control Contamination Without the Run-Around" that was Faxed to our office by John Gustafson on May 2, 1997.

We have consulted with FDA's Office of Device Evaluation and have re-reviewed your 510(k) premarket notification submission. There is no information in your 510(k) regarding either the CleanHead™ System nor the non-retraction valve. These additions to the high speed handpiece represent a significant change in the design, components, and method of manufacture as promulgated under the provisions of 21 CFR 807.81(a)(3)(1). Such changes require the submission of a new 510(k) prior to marketing the device with these design changes.

Additionally, the literature references which you submitted with your response to support your claims of stopping infection in its tracks, preventing internal contamination by expelling fluids immediately as they enter the head, and ensure that no foreign matter enters the water line due to the non-retraction valve, also requires the submission of a new 510(k) because it changes the intended use of the device as stipulated under 21 CFR 807.81(a)(3)(ii).

The NSK High Speed Air Turbine Dental Handpiece is manufactured by NSK America Corporation (NSK) and is a device within the

meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The NSK Handpiece has been cleared under section 510(k) of the Act and is intended for use in applications where high speed cutting of tooth structure is required, such as for crown preparation and dental cavity preparation. Other intended uses could include polishing of restorations and removal of existing restorative materials. This device has not received FDA clearance for the intended use of preventing infection or similar claims as identified above, nor for the non-retraction valve and/or CleanHead™ System.

Because of the above claims and changes in the design of the device, the NSK handpiece is 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 NSK Handpiece is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device were not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your NSK Handpiece. 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 the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

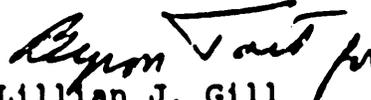
Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to 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.

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.

Page 3 - Mr. Hiroji Sekiguchi

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,



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