



MAY 10 2000

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

**WARNING LETTER**

**VIA FEDERAL EXPRESS**  
**VIA FACSIMILE**

Gerald A. Niznick, DMD  
President  
Paragon Implant Company  
15821 Ventura Boulevard  
Suite 420  
Encino, California 91436

Re: Paragon Swiss Plus Implant System,  
K953101

Dear Dr. Niznick:

The Food and Drug Administration (FDA) has reviewed two of your web sites for the Paragon Swiss Plus Implant System. The Paragon Swiss Plus Implant System (Paragon System) is manufactured by Paragon Implant Company (Paragon) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Paragon System has been cleared under section 510(k) of the Act and is intended to be placed in the maxilla and/or mandible of partially and/or totally edentulous patients, in order to restore mastication.

Both of your web sites at the Internet addresses: <http://www.paragon-implant.com> and <http://www.straumann-clone.com> make claims that the Paragon System and components are compatible with Straumann's ITI Dental Implant System and components. Representative examples of such claims are as follows:

- *If you are currently an ITI customer, you may use your existing drills to place the Swiss Plus implant*
- *PLUS apical grooves for self-tapping insertion—Use ITI or Paragon drills with Paragon's ratchet and tools*
- *PLUS Paragon's patented internal octagon platform that accepts ITI's Solid Abutment and Octabutment*

- *PLUS emergence profile, 2 piece, straight and angled abutments that cover the implant's shoulder. Compatible with Straumann's synOcta internal octagon implant*
- *Swiss Plus and synOcta share the same platform, allowing for interchangeability of prosthetic components, matching dimensions and external thread patterns allowing use of the same surgical instruments. In addition, Swiss Plus has a self-tapping vertical cutting groove and apical end for ease of insertion. Swiss Plus brings to ITI customers the prosthetic versatility that is needed to simplify procedures, improve esthetics and reduce costs*
- *Paragon's Swiss Plus transfers and abutments precisely fit ITI's synOcta Implant and ITI's solid abutments for cemented restorations and Octa Abutments for screw-retained restorations are compatible with the Swiss Plus implant's platform.*

FDA's Office of Device Evaluation (ODE) has determined that before a claim of compatibility/interchangeability between the Paragon Swiss Plus Dental Implant System and components of other manufacturers may be made (i.e., Straumann's ITI System), Paragon must submit a new 510(k) as described under the provisions of 21 CFR 807.81(a)(3)(ii). Claims of compatibility/interchangeability represent a major modification in the intended use of the device.

Continued claims of compatibility and/or interchangeability of the Paragon Swiss Plus Implant System with that of other endosseous implant manufacturers causes your device 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 Paragon Swiss Plus Implant System 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 was 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 Paragon Swiss Plus Implant System. 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.

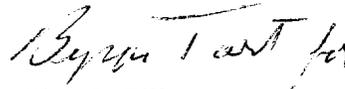
You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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.

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 Los Angeles District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Los Angeles District Office (HFR-PA200), 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely yours,



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