K023953

ST. GEORGE TECHNOLOGY, INC.

FEB 1 4 2003

Premarket Notification [510(k)] Summary

Submitted by:	St. George Technology, Inc.
Contact Person:	Vernon Watkins
Address:	P.O. Box 2849 Wilmington, NC 28402 USA
Telephone:	(910) 397-0781
Fax:	(910) 397-0791
E-mail:	Vwatkins@byegeorge.com
Date Prepared:	November 2002
Trade Name:	St. George Technology, Inc. Perfection Plus Disposable Prophy Angles
Common Name:	Disposable Prophy Angles (DPA's)
Classification Name:	Dental Contra and Right-Angle Handpiece Attachment
Predicate Device:	Young Dental Manufacturing Disposable Prophy Angle
Description Of Device:	Plastic disposable item comprising a housing (body) that holds two plastic shafts aligned at 90 degrees (right angle) to each other that rotate a cup or brush.
Intended Use:	The device is a plastic disposable attachment for use in conjunction with a slow speed handpiece, used during the professional prophylaxis treatment of patient's teeth by a dentist or hygienist.

Technological Characteristics Compared With Predicate Device:

	Device 1 **Young Manufacturing DPA** **510(k) 790722**	**St. George Technology** **Perfection Plus DPA**
Indications for Use	For single use by Dental Professional in cleaning patient's teeth.	Same
Target Population	Dentists and Hygienists	Same
Design	Plastic one-piece housing (outer body) holding 2 internal shafts aligned at 90 degree (right angle) to each other. Tip fitted with a rubber cup or brush to clean teeth.	Same
Materials	Two types of plastic with either a rubber cup or brush fitted at the cleaning tip.	Same
Performance	To be able to perform a full cleaning procedure.	Same
Sterility	Non Sterile	Same
Biocompatibility	Have caused concern with latex allergies due to cup material.	Non latex material used on all cups – Improvement
Mechanical Safety	Robust construction to withstand forces involved in a cleaning.	Same
Energy Used/ Delivered	Rotation of the cleaning device cup/brush tip provided by a slow speed hand piece	Same
Compatibility with other devices	Designed to fit securely onto most available ISO fitting standard slow speed hand pieces	Same
Where Used	Dental Office/Operatory	Same

P. O. BOX 2849 • WILMINGTON, NC 28402-2849 • USA
TEL. 910-397-0781 • FAX. 910-397-0791
TheBest@byegeorge.com

Non-Clinical Performance:	The St. George Technology, Inc. Perfection Plus Disposable Prophy Angles have been extensively tested in in-vitro environments for fit, wear, duration of performance, strength, and durability.
Conclusion From Non Clinical Test:	In all criteria the St. George Technology, Inc. Perfection Plus Disposable Prophy Angle performed satisfactorily when compared to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Vernon Watkins
President
St. George Technology, Incorporated
P.O. Box 2849
Wilmington, North Carolina 28402-2849

Re: K023953
Trade/Device Name: St. George Technology, Inc. Perfection Plus Disposable Prophy Angles
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EGS
Dated: November 26, 2002
Received: November 27, 2002

Dear Mr. Watkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ST. GEORGE TECHNOLOGY, INC.

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Statement of Indications for Use

Our disposable prophylaxis angle is intended as a single use device used by a Dental Professional, either a Dentist or a Dental Hygienist to assist in the cleaning process of patient's teeth. It is intended for a single patient and should be discarded after each patient.

Ken Mulley for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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