

**510(k) SUMMARY**  
**SIEMENS AG**  
**T1 LINE DENTAL HANDPIECES**

K972436

**1. DATE PREPARED**

June 26, 1997

**2. SUBMITTER**

Siemens AG  
Medical Technology/Dental Systems  
Fabrikstrasse 31  
64625 Bensheim  
Germany

**3. CONTACT**

Mr. Hermann Landgraf  
011-49-62-5116-2359

**4. DEVICE NAME**

Proprietary Name:	T1 LINE Dental Handpieces
Common/Usual Name:	Dental Handpiece
Classification Name:	Dental Handpiece

**5. DEVICE CLASSIFICATION**

Dental handpieces and accessories have been classified under Section 513 of the Act as Class I devices by the Dental Devices Panel.

Classification Regulation: 21 CFR 872.4200  
Product Code: 76 EFB

## **6. DEVICE DESCRIPTION AND COMPARISON TO PREDICATE PRODUCTS**

The Siemens T1 LINE Dental Handpieces are intended for use in the dental operatory to prepare dental cavities for restorations, such as fillings, and for dental cleanings. The devices can be either AC-powered or air-powered. They are reusable, ergonomically shaped, and are provided both with and without a fiber optic light system. Water delivery has optional one, two, and three spray outlets, and includes a one-way retraction valve to prevent the ingress of external air or liquid when the spray system is not in use. The device can be sterilized by the steam autoclave method.

The Siemens T1 LINE Dental handpieces are similar in design, function, and intended use to other dental handpieces currently in U.S. commercial distribution. Examples of substantially equivalent devices include the A-DEC/W&H Low Speed Handpieces.

## **7. PERFORMANCE TESTING**

The Siemens T1 LINE Dental Handpieces comply with ISO Standard 1797-1 for Dental Rotary Instruments - Shanks made of metal, ISO Standard 3964 for Dental Handpieces - Coupling dimensions, and ISO 7785-2 for Straight and geared angle handpieces. Additional performance testing was conducted on the device to validate the sterilization process and device effectiveness following 2000 sterilization cycles.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 22 1997

Diane E. Minear, RAC  
Senior Staff Consultant  
Medical Device Consultants, Incorporated  
49 Plain Street  
North Attleboro, Massachusetts 02760

Re: K972436  
Trade Name: T1 Line Dental Consultants Incorporated  
Regulatory Class: I  
Product Code: EFB  
Dated: June 27, 1997  
Received: June 30, 1997

Dear Ms. Minear:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

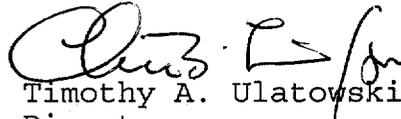
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K972436

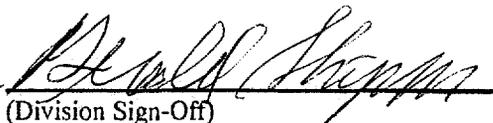
Device Name: T1 LINE DENTAL HANDPIECES

Indications For Use:

The Siemens T1 LINE dental handpieces are intended for use in the dental operatory to prepare dental cavities for restorations such as fillings, and for cleaning teeth.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

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Concurrence of CDRH, Office of Device Evaluation (ODE).....



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

510(k) Number K972436

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)