K004031

MAR 2 8 2001

XI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS. December 20, 2000.
[Separate Page]

I.* Submitter: Dr. John Schoeffel, Dental Power, Inc., Dana Point, CA.
Phone: 800-222-9515

II. Classification Names and numbers: Drill, Dental, Intraoral: DZA; File, Pulp Canal, Endodontic: EKS.

III. Common/Usual Name: Endodontic files, reamers; orifice shapers.

IV. Proprietary Names: NT Swift™ (Nickel-Titanium Endodontic Reamers); Ti\tec™ (Nickel Titanium Endodontic Reamers); Gates Glidden Drills; Dental Power™ Endodontic Hand Files

V. Establishment Registration Number: in process.

VI. Classification: Drill, Dental, Intraoral was classified by the Dental Devices Panel into Class I, described under CFR 872.4130 and the File, Pulp Canal, endodontic was classified into Class I, described under CFR 872.4565 (dental hand instrument), exempt from 510(k) requirements if made of stainless steel.

VII. Substantial Equivalence: NT Swift, Ti-tec, Gates-Glidden, and Dental Power endodontic files and rotary instruments are substantially equivalent to Tulsa Dental Products Nickel-Titanium Variable Taper Rotary Instruments, cleared under K-954790; Profile Series 29 Endodontic files, cleared under K-933582; and Gates-Glidden Drills cleared by the Hygenic Corp. under K-905418.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, as the predicated devices listed above.

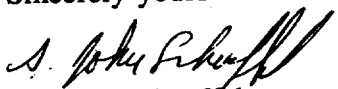
2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market except for differences in that instead of stainless steel they are made of a well established nickel-titanium alloy--as are some of the predicates.

3. Descriptive information provided shows that the materials from which NT Swift, Ti-tec,™ Gates-Glidden, and Dental Power instruments are made are substantially equivalent to (virtually identical with Tulsa Dental) those of similar products, used for identical purposes, currently on the market.

4. The FDA "Decision-Making Process" chart was used.

A specific guidance document is not available for these well-known dental instruments. However, we followed the general guidance provided on the preparation of a premarket notification--510(k). We believe we have complied fully with guidance documents and usual practices in preparing premarket notifications. If additional information or explanation is needed, please call me at 800-222-9515 or fax me at 949-489-1834. Alternately, you may contact Dr. H. N. Dunning at 301-229-2138, 8309 Bryant Dr., Bethesda, MD 20817, who is acting on my behalf, for a local response.

Sincerely yours



G. John Schoeffel
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2001

Mr. John Schoeffel
President
Dental Power, Incorporated
24422 Del Prado, #11
Dana Point, California 92629

Re: K004031
Trade Name: NT Swift; TI/TEC; Gates Glidden Drills;
Dental Power Endodontic Hand Files
Regulatory Class: I
Product Code: EKS and DZA
Dated: December 28, 2001
Received: December 28, 2001

Dear Mr. Schoeffel:

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 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). 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 (Premarket 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 premarket 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.

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" (21CFR 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/dsma/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

VIII.1 Indications for Use: [Separate Page]

510(k) Number: ~~NA~~ K004031

Device Names:

NT Swift™ (Nickel-Titanium Endodontic Reamers)
Ti\tec™ (Nickel Titanium Endodontic Reamers)
Gates Glidden Drills
Dental Power™ Endodontic Hand Files

Intended Uses:

These instruments are intended for the cleaning of pulp and other materials and the shaping of canals in "root canal" operations. They also aid in smoothing of the canal, shaping the orifice, and properly tapering the canal to allow optimum filling with various obturators.

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use_____ (Per 21 CFR 801.109)

OR

Over-The-Counter Use_____ (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K004031