

MAY 22 1997

K971319

SECTION 15

SUMMARY OF SAFETY AND EFFECTIVENESS

SECTION 15: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

15.1 SUBMITTER INFORMATION

- a. **Company Name:** Tycom Dental
- b. **Company Address:** 17802 Fitch Avenue
Irvine, CA 92714
- c. **Company Phone:** (714) 955-0800
- d. **Contact Person:** Patrick Johnson
General Manager
Tycom Dental
- e. **Date Summary Prepared:** March 27, 1997

15.2. DEVICE IDENTIFICATION

- a. **Trade/Proprietary Name:** NT and Mac Series Endodontic Files
- b. **Classification Name(s):** Pulp Canal, Endodontic File

15.3 IDENTIFICATION OF PREDICATE DEVICE

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Tycom Dental	Quantec Series 2000	K962031	June 4, 1996

15.4 DEVICE DESCRIPTION

The NT and Mac Series Endodontic Files are a series of engine (rotary) driven and hand driven endodontic files for use in root canal preparation. The files are constructed of nickel-titanium and color coded for ease of use. The files are available in 21 and 25mm lengths and ten graduating sizes.

15.5 SUBSTANTIAL EQUIVALENCE

The Mac Series Endodontic hand files are substantially equivalent to the Tycom Dental Quantec Series 2000 hand files in terms of intended use and technological characteristics. The NT Series Endodontic engine files are substantially equivalent to the Tycom Dental Quantec Series 2000 engine files in terms of intended use and technological characteristics.

The fundamental characteristics of the device are similar to those of the predicate devices and are listed on the comparison charts provided in this 510(k) submission.

15.6 INTENDED USE

The NT and Mac Series Endodontic Files are designed for use in root canal preparation.

15.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the predicate and legally marketed devices is provided in this submission.

15.8 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1997

Tycom Dental
C/O Carol L. Patterson
Consultant
Patterson Consulting Group, Incorporated
18140 Smokesignal Drive
San Diego, California 92127

Re: K971319
Trade Name: NT Series Endodontic Files, Mac Series
Endodontic Files
Regulatory Class: I
Product Code: EKS
Dated: March 27, 1997
Received: April 10, 1997

Dear Ms. Patterson:

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

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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" (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

INDICATIONS FOR USE

510(k) Number: To Be Assigned By FDA

Device Name: NT and Mac Series Endodontic Files

Indications For Use: The NT and Mac Series Endodontic Files are engine files and hand instruments designed for use in root canal preparation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rimmer
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971319

Prescription Use OR Over-The-Counter Use

(Per 21 CFR 801.109)