JUN - 4 1996 K962031

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:	May 20, 1996

15.2. DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	Quantec Series 2000 Endodontic File
b.	Classification Name(s):	IntraOral Dental Drill Dental Hand Instrument

15.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Tulsa Dental	Profile 29 Series	K933582	10/20/93
Dentsply	SureFlex Endodontic Files	K943584	09/21/94

15.4 DEVICE DESCRIPTION

The Quantec Series 2000 Endodontic Files are a series hand driven and engine (rotary) 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 17, 21 and 25mm lengths and ten graduating sizes.

15.5 SUBSTANTIAL EQUIVALENCE

The Quantec Series 2000 Endodontic hand files are substantially equivalent to the Tulsa Dental Profile 29 Series hand files and the Dentsply SureFlex Endodontic Files in terms of intended use and technological characteristics. The Quantec Series 2000 Endodontic engine files are substantially equivalent to the Tulsa Dental Profile 29 Series 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 Quantec Series 2000 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.