PRODRIVE SYSTEMS

Handpiece Performance through Innovation

K090369

510(k) SUMMARY

ProDrive Line of Dental Handpieces
ProDrive Systems Inc.

FEB 27 2009

Owned by:

ProDrive Systems Inc.
812 Commerce Drive
Ogdensburg, NY 13669
USA

Contact Person:

Timothy F. Nason, PhD
Director of Regulatory Affairs
ProDrive Systems Inc.
812 Commerce Drive
Ogdensburg, NY 13669
USA

Date of Summary:

January 9, 2009

Device Name:

Proprietary Name:	ProDrive Line of Dental Handpieces
Common Name:	dental handpiece
Classification Name:	Handpiece, Air-powered, Dental
Product Code:	EFB ("Dental handpiece and accessories", 21CFR 872.4200)

Predicate Device:

Proprietary Name:	T1 LINE Dental Handpieces
510(k) Number:	K972436
Product Code:	EFB

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Description of Device:

The ProDrive line of high-speed air-driven dental handpieces includes two models – the ProDrive Mini and ProDrive Standard. These models are each available with one of a variety of quick couplings for use with: Sirona, KaVo, W&H, Bien-Air, NSK Mach and NSK QD-J connections. In addition, the PD Standard model comes in a fixed coupling format for MidWest handpiece users.

The handpieces come supplied with a halogen light source of approximately 25,000 lux and a 3 jet spray for water. Every ProDrive handpiece is equipped with the previously-cleared ProDrive turbine as the standard drive mechanism.

The ProDrive turbine is appropriate for use with ProDrive carbide and diamond cutting instruments. A push-button spindle mechanism is used to grip the shanks of the cutting instruments. The unique geometry of the bur shank and turbine spindle securely locks the bur in the turbine eliminating the slipping that can occur over time with traditional burs and turbines. In addition to improved performance and durability, the secure locking mechanism enhances the safety of the ProDrive Replacement Turbine by reducing the risk of accidental disengagement of burs from the handpiece during operation.

In addition, the ProDrive system incorporates the ability to index the bur to a second, extended, position effectively improving on the visibility angle and the utility of the handpiece without adversely affecting its performance.

The ProDrive line of dental handpieces meets or exceeds all of the applicable performances standards outlined in ISO 7785-1:1997(E). Extensive testing indicates that after 250 sterilization/use cycles the ProDrive handpiece continues to meet all performance requirements.

Intended Use of Device:

The ProDrive Line of Dental Handpieces is intended for use by authorized persons in the practice of dentistry. The intended use of the ProDrive Line of Dental Handpieces is identical to that of the Predicate Device.

Comparison of Technological Characteristics to Predicate Device:

The following table compares the features of the ProDrive Line of Dental Handpieces to the Predicate Device:

Table 1: Substantial Equivalence Table

TECHNOLOGICAL CHARACTERISTIC	COMPARISON TO PREDICATE
Intended use	Identical
Indications for use	Identical
Target population	Identical
Anatomical sites	Identical
Where used	Identical
Energy used and/or delivered	Similar
Human factors	Similar
Design	Similar
Performance	Similar
Standards met	Identical
Materials	Similar
Biocompatibility	Identical
Compatibility with environment and other devices	Identical
Sterility	Identical
Electrical safety	Identical
Mechanical safety	Identical
Chemical Safety	Identical
Thermal safety	Identical
Radiation safety	Identical

Conclusions Drawn from Technical Comparison:

The ProDrive Line of Dental handpieces is essentially the same as the predicate device in terms of its intended use, operating principles and materials.

The ProDrive Line of Dental handpieces conforms to the ISO 7785-1:1997(E) standard and the FDA Guidance Document on Dental Handpieces.

Therefore, we conclude that the ProDrive Line of Dental handpieces is both safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2009

ProDrive Systems, Incorporated
C/0 Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K090369
Trade/Device Name: The ProDrive Line of Dental Handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: February 12, 2009
Received: February 13, 2009

Dear Mr. Job:

This letter corrects our substantially equivalent letter of February 27, 2009.

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 (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.

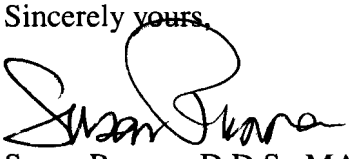
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): Not yet assigned

Device Name: The ProDrive Line of Dental Handpieces

Indications For Use: To be used in the dental operatory to prepare dental cavities for restorations such as fillings, and for cleaning teeth.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K090269