PRODRIVE SYSTEMS

K062219

510(k) SUMMARY

ProDrive Replacement Turbine
ProDrive Systems Inc.

AUG - 4 2006

Owned by:

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

Contact Person:

Clive Hooton, Vice President Quality
ProDrive Systems Inc.
812 Commerce Drive
Ogdensburg, NY 13669
USA

Date of Summary:

June 28, 2006

Device Name:

Proprietary Name:	ProDrive Replacement Turbine
Common Name:	turbine assembly for dental handpiece
Classification Name:	Handpiece, Air-powered, Dental
Product Code:	EFB ("Dental handpiece and accessories", 21CFR 872.4200)

Predicate Device:

Proprietary Name:	430 Series High Speed handpeice
510(k) Number:	K960719
Product Code:	EFA*

* Note that this handpiece is incorrectly identified in the CDRH database as EFA (handpiece, belt and/or gear driven, dental). It is, in fact, an air-powered handpiece (EFB), as is the device presented in this submission.

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Description of Device:

The ProDrive Replacement Turbine is a high-speed air-powered turbine designed to be installed in existing, legally marketed dental handpieces.

The ProDrive Replacement 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.

When fully seated, the length that the ProDrive bur extends from the handpiece is the same as that of the standard bur/turbine assembly. 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.

Because of the unique geometry of the ProDrive Replacement Turbine it is appropriate for use only in combination with ProDrive carbide and diamond cutting instruments. Standard round-shank burs will not fit into the ProDrive chuck, preventing their unintended use. ProDrive burs, however, will fit in traditional friction-grip chucks and will meet appropriate performance requirements when used in this way.

With the exception of the unique drive-lock spindle, the ProDrive Replacement Turbine consists of commercially available replacement parts currently used to refurbish dental handpieces in the United States. The spindle is composed entirely of stainless steel. The predicate device spindle is also manufactured from stainless steel. Therefore, the products are considered to be identical in materials used in their manufacture.

ProDrive burs are composed of tungsten vanadium stainless steel, coated with carbide or diamond cutting surfaces. The ProDrive burs are machined for ProDrive Systems Inc. by the bur manufacturer to the unique shank geometry required by the ProDrive drive-lock mechanism. In all other respects the burs are identical to commercially available burs currently distributed in the

United States. The use of stainless steel in the manufacture of ProDrive spindles and burs ensures biocompatibility and resistance to corrosion.

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

Intended Use of Device:

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

Comparison of Technological Characteristics to Predicate Device:

The following table compares the features of the ProDrive Replacement Turbine 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	Similar
Materials	Identical
Biocompatibility	Identical
Compatibility with environment and other devices	Similar
Sterility	Similar
Electrical safety	Identical
Mechanical safety	Similar
Chemical Safety	Identical
Thermal safety	Similar
Radiation safety	Identical

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Conclusions Drawn from Technical Comparison:

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

The ProDrive Replacement Turbine combined with ProDrive burs conform to the ISO 7785-1:1997(E) standard and the FDA Guidance Document on Dental Handpieces, which include testing and performance limits on the following characteristics:

- Extraction force
- Torque
- Eccentricity
- Speed
- Stall torque
- Resistance to corrosion
- Noise level
- Air pressure
- Sterility validation
- Reprocessing

The performance testing of the ProDrive Replacement Turbine indicates that it functions as well as or better than the predicate device in all aspects examined. Therefore, we conclude that the ProDrive Replacement Turbine 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

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

AUG - 4 2006

Re: K062219
Trade/Device Name: ProDrive Systems Replacement Turbine
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: July 31, 2006
Received: August 2, 2006

Dear Mr. Job:

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 application (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.

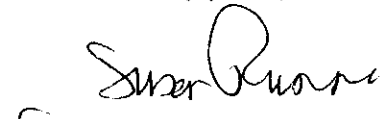
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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

Device Name: The ProDrive Replacement Turbine

Indications For Use: To be used intraorally by trained dental professionals for drilling and preparation of dental cavities for restoration, such as fillings.

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)

...ion Sign-Off)
...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number K062219