2. 510(k) SUMMARY of Safety and Effectiveness

[807.92 (c)]

2.1 Submitter [807.92 (a)(1)]

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OCT 2 2 2010

2.2 Submission Correspondent [807.92 (a)(1)]

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2.3 Date Summary Prepared [807.92 (a)(1)]

October 4, 2010

2.4 Device Names [807.92 (a)(2)]

Proprietary	**DRFP ProSmart Root Canal Obturation System** **ProPoints** (4%, 6%, PT, S) Obturation Points **ProRes** Sealer with Active Powder
Common	Root Canal Obturation Points and Sealer
Classification Names	Resin, Root Canal Filling
Product Code/ CFR	KIF Class II CFR 872.3820

2.5 Reason for Submission [807.81(3)(i)]

New Device

2.6 Predicate Devices [807.92(a)(3)]

Paste	**K042769 ADSEAL Root Canal Filling** KIF CFR 872.3820 (Sponsor: Meta Biomed Company Limited)
Obturation Points	**Class I Gutta Percha** EKM CFR 872.3850 (FDA-listed by 62 manufacturers)

2.7 Device Description [807.92(a)(4)]

The ProSmart Root Canal Obturation System is using hydrophilic polymer technology. This causes the material to expand into irregularities and tubules of the root canal to assure a tight mechanical seal with the dentine. The hydrophilic properties of the system allow extraction without softeners in revision procedures.

2.7.1 ProPoint Obturation Points

ProPoints are offered in the traditional 4% and 6% sizes and for use with variable taper files (such as ProTaper™ and Sendoline S5™). The radiopaque core is coated with hydrophilic, translucent material that expands radially up to 20% (6% points) while maintaining dimensional length stability.

The points are packaged in clean conditions and come individually wrapped to prevent cross-contamination. They can be cut to exact tip size and length.

No heating or compression equipment is required. Post insertion can commence immediately after root canal has been filled.

ProPoints are coated with ProRes paste prior to insertion into the root canal.

2.7.2 ProRes Paste

Is a two-component base:catalyst paste based on epoxy-amine resin chemistry. It is packaged in a dual-syringe for easy and consistent mixing.

The paste comes with a carefully formulated 'Active Powder'. Mixing a tiny scoop of this material into the prepared ProRes will provide the paste with hydrophilic properties that uses the moisture present in the root canal to expand into crevices and dentine tubules for a tight mechanical seal with the tooth dentine.

2.8 Statement of Intended Use [807.92(a)(5)]

The DRFP ProSmart Root Canal Obturation System is designed for permanent sealing of root canals following established endodontic procedures by qualified healthcare professionals.

The ProSmart Root Canal Obturation System is intended for Prescription Use.

2.9 Comparison with Predicate Devices [807.92(a)(6)]

2.9.1 ProPoints

Are functionally substantially equivalent to **gutta percha points** that have been used in endodontics for more than 100 years.

2.9.2 **ProRes Paste**
Is substantially equivalent to **K 042769**
ADSEAL Root Canal Filling
Meta Biomed Company Limited

2.9.3 **Hydrophilic Materials in Powder and in ProPoint Coating and ProPoint Cores**

- Hydrophilic polymers in ProPoint coatings and in ProRes powder are similar to polymers used in contact and intraocular lenses.
- ProPoint core materials are used in dental implant abutments, dental bridges and crown cores as well as in surgical sutures.

2.10. Performance Data [807.92(b)]

2.10.1 Non-Clinical PerformanceTests (807.92(b)(1)

ProRes Sealer: **Handling & Setting Characteristics**

Parameter	Acceptable Limit (ISO 6876:2001 & ANSI/ADA Specification # 57)	Results
Flow	Not less than 20mm	44mm
Working time	Not less than 90% stated by manufacturer	35 mins at 37°C
Setting time	Within range stated by manufacturer	45 mins at 37°C
Film thickness	Not more than 50µm	3.3 µm
Solubility	Shall not exceed 3%	0.0324%
Radiopacity	Not less than 3mm Al equivalent	5.4mm Al equivalent

ProSmart System:

1) **Expansion on Hydration**
Propoints coated with prores expand up to 20%.

2) **Worst Scenario Bench Test of Resistance to Tooth Cracking Due to Hydrophilic Expansion**
Insertion of **pro**res-coated **pro**points in heat-sterilized extracted teeth (more brittle and desiccated than patients' teeth), showed no sign of cracking or damage due to product expansion.

3) **Exposure to Sodium Hypochlorite**
The manufacturer's recommends to rinse the canal three (3) times prior to insertion of the system. If this regime is followed, the remaining value of 0.01% sodium hypochlorite will have no effect on the safety and effectiveness of the device.

4) **Exposure to EDTA**
Undiluted 17% EDTA has shown to have no effect on the system.

5) **Radiopacity**
Extensive testing and continuous interaction with practicing dentists after three (3) years of use in Europe demonstrate adequate radiopacity for the intended purpose. The dentist is able to

- verify that the obturation point is located in the correct position and has the correct working length

- assure that it has not penetrated the apex and as a medical record to
- assess healing

ProPoint Obturation Points:

1) **ISO 6877:2006**

All applicable performance testing showed the points to be in full compliance with this standard. Since the standard was developed with reference to traditional Gutta Percha points, additional device-specific testing was performed regarding:

- Expansion on Hydration
- Bonding of Sheath to Core
- Flexibility
- Geometry
- Radiopacity and Analysis of Core Materials
- In-Vitro Dye Penetration and Sealing Tests
- CT Scans and X-Ray Photographs

Test results demonstrate that **pro**points are safe and effective for the intended purpose.

2) **ADA/ANSI Specification # 78**

DRFP **pro**points comply with all relevant requirements. Due to device-specific material differences when compared to Gutta Percha, **pro**points differ in

- Color = white core and translucent coating
- Radiopacity = radiopaque core and radiolucent coating

propoints are visible in the filled root canal when x-rayed so that the endodontist can verify the effectiveness of the obturation

2.10.2 Clinical Evaluation (807.92(b)(2)

Radiographic images of an on-going, controlled three-year investigation to evaluate the ease of use by operating dentists, the handling characteristics and the specific root filling techniques of the ProSmart System, demonstrate after one year:

- 33% healed
- 35% improved
- 25% same periapical tissue
- 6% widening of the periodontal ligament (This is an assessment of the state of tissue surrounding the base of the tooth and not an effect caused by the ProSmart system)

All teeth treated with ProSmart Root Canal Obturation System, were

- symptom-free and in function;
- No teeth had to be extracted
- None had to be retreated or required a clinical intervention

Clinical evidence after close to three (3) years of use in Europe confirms these findings.

2.11 Contraindications

The manufacturer recommends to not use the system in pregnant women and in nursing mothers.

2.12 Information Bearing on Safety and Effectiveness
[807.92 (b)(3)]

The materials used in the DRFP ProSmart Root Canal Obturation System have a long history of safe and effective use in dental and other medical devices.

Biocompatibility testing according to ISO 10993 and ISO 7405 has shown the material to be non-toxic, non-carcinogenic and biocompatible with tissue fluids. There are no characteristics known that should adversely affect the safety and effectiveness of this device

Test data demonstrate that the DRFP ProSmart Root Canal Obturating System is substantially equivalent to its predicates.

The results of design validation and non-clinical and clinical performance testing raise no new issues of safety and effectiveness.

8/10/10
Date

Jerry Watson, BDS
CEO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DRFP Limited
C/O Ms. Dagmar Maeser
Maeser Business Support International, V.O.F.
Amstel 320-I
1017 AP Amsterdam Netherlands

OCT 2 2 2010

Re: K100248
Trade/Device Name: DRFP ProSmart Root Canal Obturation System – ProPoint 4%, 6%, PT, S Obturation Points – ProRes Root Canal Sealer
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: October 8, 2010
Received: October 12, 2010

Dear Ms. Maeser:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

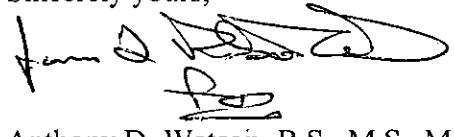
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): **K 100248**

Device Name: **DRFP ProSmart Root Canal Obturation System**
- **ProPoint** 4%, 6%, PT, S Obturation Points
- **ProRes** Root Canal Sealer

OCT 2 2 2010

INDICATION FOR USE:

The DRFP ProSmart Root Canal Obturation System is designed for permanent sealing of root canals following established endodontic procedures by qualified healthcare professionals.

Prescription Use __X__ AND/OR **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Susan Runner

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

510(k) Number: K100248

Concurrence of CDRH, Office of Device Evaluation (ODE)