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5. 510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of 21 C.F.R. part 872.3690

Date prepared: January 24, 2011

Company

Name	Silmet Ltd
Address	12 Hassadna St., Industrial Park Or Yehuda 60200. Israel
Telephone	972 3 5331474
Fax	972 3 5331581
Contact	Moshe Zalsman
e-mail	moshe@silmet.co.il

Devices

Trade Name:	**ProFil Composites** (ProFil, ProFil Flow)
Classification Name:	Tooth shade resin, material (21 CFR 872.3690)
Common Name:	Dental Composites and Filling Materials
Regulatory class:	Class II

Predicate Devices

GrandiO	(K051867, VOCO America)
Unifil Flow	(K020342, GC America)
Filtek Supreme Ultra Flowable	(K100235, 3M ESPE Dental Products)

Description

The **ProFil Composites** are light cured restorative micro hybrid composite resins for use in both posterior and anterior restorations. The restoratives are available in a variety of tooth colored shades and are packaged in syringes and capsules.

Device function, scientific concept, physical and performance characteristics

ProFil Composites are a heterogeneous blend of organic resin and inorganic filler. The proportion of these two components determines the physical properties of the restoration.
The resin matrix contains bisphenol A glycidyl dimethacrylate(Bis-GMA) and triethylene glycol dimethacrylate (TEDGMA) is added to decrease the viscosity.
The filler particles are silane-coated (for adhesion and coupling) barium silicate glass combined with 5 to 15 percent weight of very small-sized (0.04 micrometer) particles of colloidal silica. These lght-cured composites include a photo-polymerizable synthetic organic resin matrix. A radiopaque oxide is added to make the composite fillings visible on radiographs.

Device components

Resin Matrix: BISGMA (bisphenol A-glycidyl methacrylate) and TEGDMA (Triethyleneglycol dimethacrylate)

Filler particles: Silica filler
Barium silicate glass combined with 5-15% weight of very small-sized (0.04 µm) particles of colloidal silica.

Filler type: Micro hybrid

- the fillers are a mixture of different particle sizes all less than one micron (very fine colloidal silica particles, approx 0.04 microns). The extremely small filler particles lend superior polishability and allow for finer color characterization, while the composite, as a whole, remains about 70% -80% filled.

The polymer materials are blended together with the finely divided inorganic material such as a barium aluminosilicate glass with a trace of radiopaque oxide that renders the resultant glass radiopaque to x-rays.

Activation system: Light cured composites, photochemical initiation causes polymerization. The composites cure under halogen or LED lights (blue light)[1]

Indication for use

Products	Indications for Use
ProFil	Direct anterior & posterior restorations Core Build ups Splinting
ProFil Flow	Class III, V & smaller Class IV restorations Base/liner in Class I & Class II restorations Repair resin, porcelain & acrylic temporary materials Pit & fissure sealant Undercut blockout Restoration of minimally invasive cavity preparations

Contraindications
Patients with allergies to methacrylate monomers

1 See IFU curing time table

Table 1: Technological characteristics

Components			Function
Fillers			
Barium aluminosilicate Fumed silica			Reduces thermal expansion coefficient and overall shrinkage. Improves handling and aesthetic results[2] Provides radio-opacity
	ProFil	ProFil Flow	
Weight of filler:	78%	60%	
Volume of filler:	59%	42%	
Particle size	0.01-3µm	0.01-2.5µm	
Resin matrix			
BIS-GMA (bisphenol glycidylmethacrylate)			These form highly cross linked polymer structures that results in a rigid resin matrix that is highly resistant to softening/degradation by heat and solvents.
TEDGMA (Triethyleneglycol dimethacrylate)			Diluent - Increases flow and handling characteristics or provide cross linking for improved strength
Butylated hydroxytoluence			Stabilizer:Controls the reaction of activators and resin mixtures, added to avoid spontaneous polymerization Extend storage lifetime Ensure sufficient working time
Camphoroquinone			Photochemical initiator: interact with the amine to form free radicals that initiate polymerization

Summary of Physical Tests

This 510(k) submission includes data from bench testing to evaluate the performance of the ProFil Composites compared to predicate devices GrandiO, Unifil Flow and Filtek Supreme Ultra Flowable. Properties evaluated include:

Compressive Strength	Diametral Tensile Strength
Flexural Strength	Flexural Modulus
Surface Hardness	Radiopacity
Water sorption	Water solubility
Polymerization shrinkage	

2 The clinical choice of a composite must consider whether priority should be given to mechanical or aesthetic requirements: if mechanical considerations are paramount the material with the greatest volume of filler will be chosen; if aesthetic considerations predominate, particle size will be the most important factor.

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Substantial Equivalence

The information provided in this 510(k) submission shows that the ProFil Composites are substantially equivalent to:

GrandiO (**K051867**, VOCO America)
Unifil Flow (**K020342**, GC America)
Filtek Supreme Ultra Flowable (**K100235**, 3M ESPE Dental Products)

The equivalence is in terms of intended use, indications for use, composition, physical properties and technological characteristics. A comparison of technological characteristics is provided below.

Table 2: Similarity of Technological properties to predicate devices

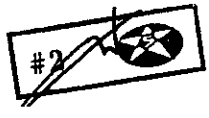
Technological property	**ProFil Composites**	**GrandiO (VOCO) K051867**	**UniFil Flow (GC America) K020342**	**Filtek Supreme Ultra Flowable (3M ESPE) K100235**
Camphorquinone/amine photoinitiator system	X	X	X	X
Mehtacrylate-based resin matrix	X	X	X	X
Silane treated fillers	X	X	X	X
Bonded with a permanent dental adhesive	X	X	X	X
When irradiated by light, the mehtacrylate functionalities of the resins and surface treated fillers undergo, in conjunction with the photointitiator system, a light induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive	X	X	X	X

The prior use of all the components in the legally marketed predicate devices supports our decision that additional testing for bio-compatibility with the final formulation are not necessary.

We believe that the prior use of these components in legally marketed devices and the performance data and results support the safety and effectiveness of **ProFil Composites** for the intended use.

Conclusion

In accordance with 21 C.F.R. part 807 and FDA's " Guidance for the preparation of Premarket Notifications for Dental Composites" and based on the information provided in this premarket notification, Silmet Ltd. concludes that **ProFil Composites** are safe and effective and substantially equivalent to the predicate devices described herein.

SILMET LTD. 24 January 2011 CEO: Moshe Zalsman Signature: 

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

Mr. Moshe Zalsman
CEO
SILMET Limited
12 Hasadna
Or Yehuda
ISRAEL 60200

FEB - 2 2011

Re: K103190
Trade/Device Name: ProFil Composites (ProFil, ProFil Flow)
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin, Material
Regulatory Class: II
Product Code: EBF
Dated: January 31, 2011
Received: January 31, 2011

Dear Mr. Zalsman:

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,

for

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

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4. Indications for Use Statement

510(k) Number (if known): K103190

Device Name: ProFil Composites (ProFil, ProFil Flow)

Products	Indications for Use
ProFil	Direct anterior & posterior restorations Core Build ups Splinting
ProFil Flow	Class III, V & smaller Class IV restorations Base/liner in Class I & Class II restorations Repair resin, porcelain & acrylic temporary materials Pit & fissure sealant Undercut blockout Restoration of minimally invasive cavity preparations

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K103190

SILMET LTD. 12 Hassadna St. Industrial Park. Or Yehuda 60200 Israel. Tel: + 972 3 5331474 Fax: +972 3 5331581 e-mail:info@silmetdental.com www.silmetdental.com