FEB 7 2000

K994304

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Ihr Zeichen yr. ref.	Ihre Nachricht vom dtd.	Unser Zeichen our ref.	Datum date

510(k) SUMMARY

ARABESK® FLOW
(76 EBF)

1. SUBMITTER'S NAME
2. CONTACT PERSON for VOCO GmbH
3. DATE THAT 510(k) SUMMARY WAS PREPARED
4. NAME OF THE MEDICAL DEVICE (Classification / Common / Proprietary)
5. LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED
6. DESCRIPTION OF THE DEVICE
7. INTENDED USE OF THE DEVICE
8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES
9. SUMMARY OF PRECLINICAL PERFORMANCE STUDIES AND CONCLUSIONS FROM PRECLINICAL PERFORMANCE STUDIES

1. SUBMITTER'S NAME
VOCO GmbH Anton-Flettner-Str. 1-3 27472 Cuxhaven GERMANY
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FO 00042 0699 99

2.	*U.S. REGULATORY CONTACT PERSON FOR VOCO GmbH*
	Evan Dick, Ph.D. E.G. Dick & Associates 7527 Westmoreland Avenue St. Louis, MO 63105
	Tel: (314) 721-0112 Fax: (314) 721-7591

3.	*DATE THAT 510(k) SUMMARY WAS PREPARED*
	December 21, 1999

4.	*NAME OF THE MEDICAL DEVICE*	
	Classification name	*Material, tooth shade, resin* (Dental 76 EBF)
	Common / usual name	*Flowable, light-curing composite filling material*
	Proprietary names	*ARABESK® FLOW*

5.	*LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED*
	• Tetric Flow (K964285, Ivoclar) • Flow Line (K990756, Kulzer)

6. DESCRIPTION OF THE DEVICE

Arabesk Flow is a light-curing and radiopaque glass ceramic microhybrid composite. It is suited for fillings in both anterior and posterior applications. Arabesk Flow's low viscosity results in excellent wetting and adhesion to the tooth. Arabesk Flow produces a high strength and color stable restoration that can be polished to a high gloss. Arabesk Flow is polymerized (cured) by halogen light. Arabesk Flow conforms well to cavity surfaces, helps to avoid trapped air, and speeds cavity filling.

Arabesk Flow contains 69% inorganic fillers (highly pure silica and barium/strontium borosilicate glass particles - average size 0.7μm) and 30% dimethacrylates (BIS-GMA, urethane dimethacrylate, triethyleneglycol dimethacryrlate).

Arabesk Flow is available in bulk dispensing syringes (3gm each) and in single-use applicator-tip capsules (0.25 gm each).

7. INTENDED USE OF THE DEVICE

Arabesk Flow is a composite filling material for both anterior and posterior applications, as well as for inlay techniques. Indications for use are:

- Fillings requiring minimally invasive preparation
- Fillings for small cavities
- Extended fissure sealing
- Substitute fillings of cavities with undercuts
- Class III-V fillings including V-shaped defects and cervical caries
- Repair of fillings and veneers
- Luting of translucent prosthetic pieces (e.g., procelain-only crowns)

8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES

Arabesk Flow, Tetric Flow (K964285), and Flow Line (K990756) are all flowable, light-curing, glass ceramic composite filling materials for use in both anterior and posterior sites.

Arabesk Flow, Tetric Flow, and Flow Line are all composed of inorganic silicates (~60-70%, w/w), dimethacrylates (~30-40%, w/w), photoinitiators and pigments (~1%. w/w). The subject and predicate devices are substantially alike with respect to such performance properties as viscosity, compressive strength, polymerization shrinkage, color stability, and resistance to abrasion.

9. SUMMARY OF PRECLINICAL PERFORMANCE STUDIES AND CONCLUSIONS FROM PRECLINICAL PERFORMANCE STUDIES

Arabesk Flow is formulated from chemical components that are commonly associated with currently marketed dental composite materials.

The chemistry of Arabesk Flow raises no new issues or questions that effect safety, effectiveness, or biocompatibility for a dental composite product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2000

Evan G. Dick, Ph.D.
c/o E.G. Dick & Associates
7527 Westmorland Avenue
St. Louis, Missouri 63105

Re: K994304
Trade Name: Material, tooth shade, resin (Dental 76 EBF)
Regulatory Class: II
Product Code: EBF
Dated: December 21, 1999
Received: December 21, 1999

Dear Mr. Dick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K994304

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K994304

Device Name: Arabesk® Flow

Indications For Use:

Arabesk Flow® is a flowable, light-curing and radiopaque glass ceramic microhybrid composite. It is suitable for restorations in both anterior and posterior applications. Arabesk® Flow is intended for:

- fillings requiring minimally invasive preparation
- fillings for small cavities
- extended fissure sealing
- substitute fillings of cavities with undercuts
- Class III-V fillings including V-shaped defects and cervical caries
- repair of fillings and veneers
- luting of translucent prosthetic pieces (e.g., procelain-only crowns)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994304