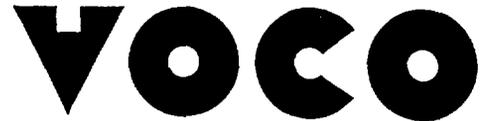


JAN 12 2000



VOCO GmbH · Postfach 767 · 27457 Cuxhaven

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27472 Cuxhaven (Germany)
Telefon: (0 47 21) 719-0
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Telex: 2 32 202 dent d

K994056

Ihr Zeichen
yr. ref.

Ihre Nachricht vom
dtd.

Unser Zeichen
our ref.

Datum
date

510(k) SUMMARY

ADMIRA®
(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
Tel: 011-49 47 21 719 0 Fax: 011-49 47 21 719 140

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
November 30, 1999

4. NAME OF THE MEDICAL DEVICE	
Classification name	<i>Material, tooth shade, resin (Dental 76 EBF)</i>
Common / usual name	<i>Light-cured dental restorative material</i>
Proprietary names	<i>ADMIRA®</i>

5. LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED
Dyract AP (K973235, DENTSPLY) Solobond M (K980539, VOCO)

6. DESCRIPTION OF THE DEVICE

Admira is a universal, light-cured restorative material based on 3-dimensionally stabilized, inorganic/organic polymers (ormocers). Patent-protected ormocer chemistry provides exceptional strength, abrasion resistance, and hard tissue adhesion, while making Admira easy and fast to use. Admira further combines the benefits of silicate glass with the strength, durability, and cosmetic advantages of composites. Admira is suitable for restorations in both anterior and posterior teeth. Admira is used with Admira Bond, a bonding agent that has been specifically designed for the total-etch technique.

Admira is available in both 4gm syringes, and as pre-dosed (0.25gm) Admira Caps (composite application system) for direct intra-oral application. Admira is available in ten tooth shades.

7. INTENDED USE OF THE DEVICE

Admira is a universal, light-cured restorative material. Admira is intended to be used for the following types of restorations in both anterior and posterior teeth:

- class I-V fillings
- reconstruction of traumatically affected anteriors
- faceting of discolored anteriors
- correction of shape and shade to improve aesthetic appearance
- locking or splinting of loose anteriors
- repairing veneers
- core build-up under crowns
- composite inlays

8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES

ADMIRA and DYRACT AP (K973235) are both single-component, light-cured, universal composites composed of silicate glass, polyacrylic/polymethacrylic acid copolymers, photoinitiators, and stabilizers. Both products are used along with a dental bonding agent designed for the total-etch technique.

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

Admira and Admira Bond (the bonding agent for Admira) are formulated from chemical components that are commonly associated with currently marketed dental composite materials.

The chemistry of Admira and Admira Bond 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

JAN 12 2000

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

Re: K994056
Trade Name: Material, Tooth Shade, Resin (Dental 76 EBF)
Regulatory Class: II
Product Code: EBF
Dated: November 30, 1999
Received: November 30, 1999

Dear Dr. 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 (Pre-market 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 pre-market notification submission does not affect any

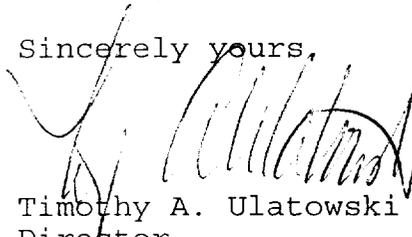
Page 2 - Dr. Dick

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

K994056

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K994056

Device Name: Admira

Indications For Use:

Admira is a universal, light-cured restorative material. Admira is intended to be used for the following types of restorations in both anterior and posterior teeth:

- class I-V fillings
- reconstruction of traumatically affected anteriors
- faceting of discolored anteriors
- correction of shape and shade to improve aesthetic appearance
- locking or splinting of loose anteriors
- repairing veneers
- core build-up under crowns
- composite inlays

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(per 21 CFR 801.109)

OR Over-The-Counter Use _____

Susan Russo

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994056