K031494

NOV 12 2003

APPENDIX C

SUMMARY OF SAFETY AND EFFICACY

(per 21 CFR 807.92)

I. Applicant:

Cooley & Cooley, Ltd.
8550 Westland West Blvd
Houston, Texas 77041 USA
281 / 897-0009 telephone
281 / 897-8040 facsimile

Contact Person: M. Joyce Heinrich
713 / 777-5477 telephone
713 / 777-6664 facsimile
tabs1@tabs.net e-mail

Date Prepared: May 9, 2003

II. Device Name

Proprietary Name:	Doc's Best White Copper Cement
Common / Usual Name:	Dental Cement
Classification Name:	Cement, Dental (21 CFR 872.3275)
Classification:	Class II
Product Code:	EMA

III. Predicate Devices

The Doc's Best White Copper Cement is substantially equivalent to Cooley & Cooley, Ltd.'s Doc's Best Red Copper Cement and other dental cements currently in commercial distribution. The Doc's Best Red Copper Cement was in commercial distribution prior to the Medical Device Amendments issued May 28, 1976. The other predicate devices include the 3M Vitremer Luting Cement (K933139), 3M RelyX Luting Cement (K022476), 3M ESPE UNICEM (K020256) and Dentsply Intl Temporary Dental Cement (K895487). These devices were cleared for introduction into interstate commerce via the FDA's 510(k) Notification process. The Doc's Best White Copper Cement has the same indications for use and similar technological and chemical characteristics as the predicate devices.

IV. Intended Use of the Device

The Doc's Best White Copper Cement is intended for use in luting of all types of restorations (e.g., ceramic, composition, metal) inclusive of bridges and crowns, inlays and onlays, attachments, pins and posts, orthodontic appliances, and cavity liners and primary teeth cavity fillings.

V. Device Description

The Doc's Best White Copper Cement is a powder that is mixed with an approved aqueous liquid to form a self-curing adhesive cement.

The cement is used in the luting of restoration of bridges and crowns, orthodontic appliances as well as cavity liners and primary teeth cavity fillings. The product is provided as a two-part product requiring mixing prior to use. Detail instructions for use are provided in the package insert accompanying the product.

VI. Performance and Safety

Cooley & Cooley, Ltd. has provided performance and safety documentation in conformance with FDA requirements provided in the guidance documents entitled "Dental Cements - Premarket Notification" (issued August 1998).

VII. Conclusions

It is the Company's belief that Doc's Best White Copper Cement is substantially equivalent to the aforementioned predicate devices in that it has the same indications for use and similar technological and chemical characteristics. Doc's Best White Copper Cement performs as intended and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2003

Cooley & Cooley, Limited
C/O Ms. M. Joyce Heinrich
Regulatory Consultant
Texas Applied Biomedical Services
12101-A Cullen Boulevard
Houston, Texas 77047

Re: K031494
Trade/Device Name: Doc's Best White Copper Cement
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: August 11, 2003
Received: August 15, 2003

Dear Ms. Heinrich:

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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

K031494

APPENDIX B

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): Pending

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

510(k) Number: K031494

Device Name:

Doc's Best White Copper Cement

Indications for Use:

The Doc's Best White Copper Cement is a dental cement system for use in:

1. Luting porcelain to metal crowns and bridges to tooth structure, amalgam, composite or glass isomer core building;
2. Luting metal inlays, on lays or crowns;
3. Luting pre-fabricated and cast posts;
4. Luting orthodontic appliances;
5. Cavity liners;
6. Primary teeth cavity fillings

(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) **(Optional Format 1-2-96)**

(Division Sign-Off)

510(k) Number: Pending