JUN 12 2012

# 510(k) Summary

Submitter: Dr. John Banky

Dentist In A Box Pty Ltd.

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Date Prepared: March 4, 2012

**Name of Device and Classification:**

Trade Name: Dentist In A Box™ Dental Emergency Kit Plus Tooth Trauma Care Kit

Common Name: Dental Emergency Kit Plus Tooth Trauma Care Kit

Classification Name: Convenience Kit

Classification: Class II (According to FDA guidance, the classification of a kit is based on the highest classification of the devices that are provided in the kit. In the case of *Dental Emergency Kit Plus Tooth Trauma Care Kit*, the highest class device is Class II.

Product Code: TBD

Predicate Device: There is one Class II device subject to a predicate in the Convenience Kit and is it's own predicate; Cavit-W temporary crown and bridge resin K875133. It is assembled into the kit as packaged from the manufacturer.

**Device Description and Predicate Device:**

Dentist In A Box intends to assemble U.S. FDA regulatory cleared and/or exempt devices into a convenience kit for the U.S. market.

The kit components are either (1) legally marketed pre-Amendments devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulation(s) and the limitation of exemptions for Section 510(k) of the act (e.g., 862.9), or (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is to be intended (i.e., not claiming or causing a new use for the component(s)).

The components are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their pre-Amendments, exemption, or premarket notification criteria and status.

Dentist In A Box Convenience Kit Components

| Quantity | Component | Use in the kit |
|---|---|---|
| 1 | Hand-held mouth mirror | Visualize traumatized, injured area |
| Pack of 2 | Sterile Cotton-tipped swabs | Used to apply temporary filling material |
| 1 x 7 gram tube | Temporary filling material | Temporary restoration to be applied to exposed tooth surfaces |
| 1 package | Tooth splinting material | Support injured tooth molding between injured and non-injured neighboring tooth |
| 5 ml | Sterile unbuffered Saline Solution 0.9%, 5ml unit dose | Rinse dirt from tooth as necessary and as storage medium for avulsed tooth |
| 1 pair package | Sterile Disposable gloves | Provides a barrier against potentially infectious materials and other contaminants |

## Intended Use/Indications for Use - 21 CFR 807.92(a)(5):

### Intended Use

The Dentist In A Box™ Dental Emergency Kit Plus Tooth Trauma Care Kit provides immediate, temporary relief from common dental problems, accidents and trauma until a dentist can be seen. For use by trained professionals.

### Indications for Use

For temporary relief from a lost filling, chipped tooth, or irritation by orthodontic wire or denture clasp or for temporary stabilization of a loosened or knocked out permanent tooth. Used by persons in remote areas such as during military field service when access to a dentist or dental equipment and facilities are not available for an extended period of time and effective treatment is necessary to prevent discomfort or delay in treatment may aggravate the injury.

**Technological Characteristic:**

The only class II device subject of comparison to a predicate in the Dental Emergency Kit Plus Tooth Trauma Care Kit is Cavit-W temporary crown and bridge resin K875133. All components in the convenience kit including the Cavit-W are assembled into the kit as packaged from the manufacturer. The device is unchanged thus technological characteristics are same.

**Expiration Date**

Expiration dating of the components are as follows:

Cotton-tipped swabs = 3 years

Cavit™ W Temporary filling material = 18 months

Eakin Cohesive Skin Barriers and Seals = stable, no expiration

Sterile unbuffered Saline Solution 0.9%, 5ml unit dose = 3 years

Sterile Disposable gloves = 3 years

The expiration date of the kit will be 18 months or the expiration date of the shortest dated component in the kit that have printed expiration dates on the packaging as received from the manufacturer; whichever is shorter.

**Non-Clinical Test Summaries: N/A**

**Clinical Study Summary: N/A**

**Conclusion:**

Based upon the information provided, The Dentist In A Box™ Dental Emergency Kit Plus Tooth Trauma Care Kit is substantially equivalent to the predicate

devices for the stated intended use. All components of the convenience kit have been found to be substantially equivalent through the premarket notification process or are exempt from premarket notification.

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. John Banky
Owner and President
Dentist In A Box Pty Ltd.
44 Horace Street
Malvern, Victoria
AUSTRIA 3144

JUN 12 2012

Re: K120695
Trade/Device Name: Dentist In A Box™ Dental Emergency Kit Plus Tooth Trauma Care Kit
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: I
Product Code: EMB
Dated: June 7, 2012
Received: June 8, 2012

Dear Mr. Banky:

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

510(k) Number (if known): K120695

Device Name: Dentist In A Box™ Dental Emergency Kit Plus Tooth Trauma Care Kit

Intended Use:

The Dentist In A Box™ Dental Emergency Kit Plus Tooth Trauma Care Kit provides immediate, temporary relief from common dental problems, accidents and trauma until a dentist can be seen. For use by trained professionals.

Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120695

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

510(k) Number: ___

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