K091380

JUL 30 2009

April 24, 2009

510(k) SUMMARY

1) Submission Applicant & Correspondent:

Name: Centrix Incorporated
Address: 770 River Road, Shelton, Connecticut 06484 USA
Establishment Registration Number 1281412
Phone (203) 929-5582
Contact Person: John Discko, Executive VP Extension 206

2) Name of Device: Cord, Retraction
Trade/Proprietary/Model Name: CordCap™
Classification Product Code: MVL

3) Devices to Which New Device is Substantially Equivalent:
Ultrapak NEHA (K010070)
Stay-Put Impregnated (K041023)

4) Device Description:
CordCap™ is a compression roll manufactured out of wicking paper and impregnated with natural salts.

5) Intended Use of the Device: The CordCap is intended for the temporary retraction and hemostasis of the gingival margin through mechanical means. Compression of gingival tissue over several minutes is commonly known to widen the sulcus. In addition, mechanical pressure on the tissue can effect hemostasis, and is enhanced through the natural action of salts.

6) Summary of Technological Characteristics of the Device Compared to the Predicate Devices:
CordCap is substantially equivalent to other legally marketed devices in the United States. CordCap™ functions in a physical manner similar to and is intended for the same use as the products Ultrapak NEHA (K010070) and Stay-Put Impregnated (K041023) cleared for marketing for Ultradent Products and Coltene/Whaledent, respectively.

In summary, CordCap ™ as described in this submission is, in our opinion, substantially equivalent to the predicate devices by meeting the following standards set by FDA:
>It has the same intended use as the predicate devices; and
>It has the same technological characteristics as the predicate devices; or
>the sponsor demonstrates that the device is as safe and effective as the legally marketed device.

7) Tests and Conclusions:
CordCap™ is a mechanical device, made of absorbent paper, and infused with sodium chloride and/or aluminum chloride salts. Salt level is less than 6mg per 1" x ½" of paper. Typically, this amounts to .06g - .09g of salt per device, depending on size. Based on the low concentrations of the above common salts, the CordCap can be considered safe and effective for the temporary retraction of gingival tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

Mr. John Discko
Executive, Vice President
Centrix, Incorporated
770 River Road
Shelton, Connecticut 06484

Re: K091380
Trade/Device Name: CordCap™
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MVL
Dated: April 24, 2009
Received: May 11, 2009

Dear Mr. Discko:

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 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.

(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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., M.A.
Acting Division 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) K091380

Device Name: CordCap™

Indications for Use: CordCap™ is intended for the temporary retraction and hemostasis of the gingival margin through mechanical means.

(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)

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

510(k) Number: K091380