510(K) SUMMARY

(As Required by Section 807.92 (c))

1. Submitter
   Name: Unicare Biomedical, Inc.
   Address: 22971-B Triton Way, Laguna Hills, CA 92653
   Contact: Stan Yang, 949-643-6707
   Date: March 3, 2009

2. Device Name
   Trade Name: Benacel® Dental Dressing
   Common Name: Wound Dressing
   Classification Name: Dressing
   Device Classification: Unclassified

3. Predicate Devices
   SaliCept®, “Sock It” oral pain gel, Hemcon®

4. Device Description
   Benacel® Dental Dressing is an absorbable wound dressing made of oxidized
   regenerated cellulose material. Upon contact with moist oral mucosa, the material
   dissolves and transforms into a gelatinous material. By applying gentle pressure at
   this time, the material will adhere to the wound and form a barrier, protecting the
   wound from further irritation and pain. Benacel® Dental Dressing is sterile
   packaged and supplied in a variety of configurations and sizes.

5. Intended Use
   Benacel® Dental Dressing is intended for use as a wound dressing in extraction sites
   and the management of alveolar osteitis (dry socket) and may be used as a wound
   dressing for the temporary management of oral surgical wounds, such as operative,
   postoperative, donor sites, and traumatic injuries. Benacel® Dental Dressing may
   also be used as a wound dressing for the management and protection of oral lesions,
including sores, ulcers, and injuries, such as cuts, lacerations and abrasions of the oral mucosa.

6. Comparison with Predicate Devices
Benacel® Dental Dressing is substantially equivalent to devices currently in US commercial distribution, including SaliCept®, “Sock It” oral pain gel and Hemcon®, These products are made of biocompatible wound dressing material with similar performance.

7. Device Testing
In vitro and in vivo tests demonstrate that Benacel® Dental Dressing performs substantially equivalent to predicate devices.
Mr. Stan Yang  
Vice President  
Unicare Biomedical, Incorporated  
22971 Triton Way, Unit B  
Laguna Hills, California  92653  

Re:  K090612  
Trade/Device Name: Benacel® Dental Dressing  
Regulation Number: Unclassified  
Regulation Name: None  
Regulatory Class: Unclassified  
Product Code: MGQ  
Dated: July 15, 2009  
Received: July 21, 2009  

Dear Mr. Yang:

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.
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” (21 CFR 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, 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
Indications for Use

510(k) Number (if known): **K090612**

Device Name: **Benacel® Dental Dressing**

Indications for Use:

Benacel® Dental Dressing is intended for use as a wound dressing in extraction sites and the management of alveolar osteitis (dry socket) and may be used as a wound dressing for the temporary management of oral surgical wounds, such as operative, postoperative, donor sites, and traumatic injuries. Benacel® Dental Dressing may also be used as a wound dressing for the management and protection of oral lesions, including sores, ulcers, and injuries, such as cuts, lacerations and abrasions of the oral mucosa.

Prescription Use **X** 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: **K090612**