



Food and Drug Administration
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November 5, 2015

BenQ Materials Corporation
Ms. Kenix Chang
Regulatory Affairs Specialist
29, Jianguo E. Road
Gueshan 33341
Taoyuan, Taiwan (R.O.C)

Re: K150963
Trade/Device Name: AnsCare ChitoClot Pad
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 29, 2015
Received: October 5, 2015

Dear Ms. Chang:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K150963

Device Name
AnsCare ChitoClot Pad

Indications for Use (Describe)

AnsCare ChitoClot Pad is indicated for use of bleeding wound management. It promotes rapid control of wound bleeding and exudates absorption.

AnsCare ChitoClot Pad is indicated for use in wound management and to provide barrier to bacteria.

It is indicated for the following wounds, including lacerations, abrasions, hemodialysis wound and puncture sites for vascular procedures.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

- 5.1 Type of Submission:** Traditional
- 5.2 Preparation Date:** April 2, 2015
- 5.3 Submitter:** BenQ Materials Corporation
- Address:** 29, Jianguo E. Rd., Gueishan 33341,
Taoyuan, Taiwan (R.O.C)
- Phone:** +886-3-3748800
- Fax:** +886-3-3763030
- Contact:** Kenix Chang, Regulatory Affairs Specialist
(Kenix.Chang@BenQMaterials.com)
- 5.4 Identification of the Device:**
- Proprietary/Trade name:** AnsCare ChitoClot Pad
- Classification Name:** Dressing, Wound, Drug
- Device Classification:** Unclassified
- Regulation Number:** —
- Panel:** General & Plastic Surgery
- Product Code:** FRO
- 5.5 Identification of the Predicate Device:**
- Predicate Device Name:** Clo-Sur^{PLUS} P.A.D.
- Manufacturer:** Scion Cardio-Vascular, Inc.
- Classification Name:** Dressing, Wound, Drug
- Device Classification:** Unclassified
- Regulation Number:** —
- Panel:** General & Plastic Surgery
- Product Code:** FRO
- 510(k) Number:** K032986

5.6 Intended Use and Indications for Use of the subject device.

AnsCare ChitoClot Pad is indicated for use of bleeding wound management. It promotes rapid control of wound bleeding and exudates absorption.

AnsCare ChitoClot Pad is indicated for use in wound management and to provide barrier to bacteria.

It is indicated for the following wounds, including lacerations, abrasions, hemodialysis wound and puncture sites for vascular procedures.

5.7 Device Description

AnsCare ChitoClot Pad is made from cross-linked chitosan with glutaraldehyde. It works as a topical wound dressing intended to promote hemostasis when in contact with a bleeding wound. AnsCare ChitoClot Pad is made from chitosan whose hemostatic effect is independent of anticoagulant. Chitosan has a long clinical history of safety and effectiveness.

5.8 Non-clinical Testing

A series of non-clinical studies were conducted on the proposed device. All the test results demonstrate that AnsCare ChitoClot Pad meet the requirements of its pre-defined acceptance criteria and intended uses.

Biocompatibility testing:

- *In Vitro* Cytotoxicity Test
- Skin Irritation Study in White Rabbits
- Skin Sensitization Study in Guinea Pigs
- Acute Intravenous Systemic Toxicity Study in Mice
- Acute Intraperitoneal Systemic Toxicity Study in Mice
- Hemolysis Test
- Pyrogen Test in White Rabbits

Bench performance testing:

- Absorbency Testing

- pH Testing
- Dimension and weight Testing
- Barrier to bacteria Testing
- Competitor analysis

5.9 Substantial Equivalence Determination

The AnsCare ChitoClot Pad submitted in this 510(k) file is substantially equivalent in intended use, main materials, design, safety and performance claims to the cleared Clo-Sur^{PLUS} P.A.D. (K032986). Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

	Proposed device	Predicate device
Item	AnsCare ChitoClot Pad	Clo-Sur ^{PLUS} P.A.D.
K number	—	K032986
Regulation Number	—	—
Classification	Unclassified	Unclassified
Product Code	FRO	FRO
Indications for Use	<p>AnsCare ChitoClot Pad is indicated for use of bleeding wound management. It promotes rapid control of wound bleeding and exudates absorption.</p> <p>AnsCare ChitoClot Pad is indicated for use in wound management and to provide barrier to bacteria.</p> <p>It is indicated for the following wounds, including lacerations, abrasions, hemodialysis wound and puncture sites for vascular procedures.</p>	<p>The Scion Cardio-Vascular Clo-Sur^{PLUS} P.A.D., is intended for the local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy.</p> <p>The dressing is indicated for the following wounds: lacerations, abrasions, nose bleeds and the skin</p>

		surface puncture sites for vascular procedures, percutaneous catheters or tubes.
Anatomical Site	External wounds	External wounds
Material	Poly D-glucosamine and poly N-acetylglucosamine derived from chitosan	Poly D-glucosamine and poly N-acetylglucosamine derived from chitosan
Sterility	Gamma irradiation	Gamma irradiation
Package material	foil bag	foil bag
Quantity	1 Pc/Box	10 Pc/Box
Size	2 x 3 cm 2 x 6 cm 6 x 6 cm 3 x 3 cm	4 x 4 cm

5.10 Similarity and differences

The differences between the proposed device and the predicate device are size and quantity. The proposed device has tested on safety and performance and the results were complied with the test requests. Therefore, the difference of proposed device and predicate device did not raise any problems of safety or effectiveness. The proposed device is substantially equivalent to the predicate device in intended use, design and performance claims.

5.11 Conclusion

After analyzing bench tests, device description and intended use/indications for use, it can be concluded that AnsCare ChitoClot Pad is as safe and effective as the predicate device.