DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 23, 2016

Shenzhen Yuanxing Nano-Pharma Co., Ltd.
Mr. Long Yang
Shenzhen Hlongmed Biotech Company
R15-08, East Building, Yihai Plaza, Chuangye Road, Nanshan District
Shenzhen, Guangdong, P.R. China 518057

Re: K152544
Trade/Device Name: Agem Ag Mesh Dressing with Silver
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 14, 2016
Received: April 21, 2016

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. 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,

Jennifer R. Stevenson -A

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152544

Device Name

Agem® Ag Mesh Dressing with Silver
Model & Specification: 5cm ×5cm, 10cm×12cm, 10cm×20cm, 20cm×20cm

Indications for Use *(Describe)*

Under the supervision of a health care professional, this dressing may be used as a primary wound dressing over:
• abrasions
• ulcers
• trauma wounds
• surgical wounds
• first and second degree burns
• donor sites
This product is not designed, sold or intended for use except as indicated.

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.

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Shenzhen Yuanxing Pharmaceutical Co., Ltd

510(K) SUMMARY

(as required by 807.92(c))

The assigned 510(K) number is: K152544

Date of Summary: May 23,2016

1. Submitter information

Manufacturer Name: Shenzhen Yuanxing Pharmaceutical Co., Ltd

Address: Room 1001, Resources-Tech-Building, No1, Songpingshan Rd., Hi-Tech Industrial Park, Nanshan District, 518057 Shenzhen, China

Contact Person and Title: LIU Longqing/ Administrative representative

Tel: 0086-755-26740339

Fax: 0086-755-26968906

Email: llq@thyx.com

2. Contact person

2.1 Primary Contact Person

Long Yang (COO)

Shenzhen Hlongmed Biotech Company

R1508, East Building, Yihai Plaza, Chuangye Road, Nanshan District, Shenzhen, P.R. China

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E-mail: yanglong@hlongmed.com

2.2 Secondary Contact Person

LIU Longqing(Administrative representative)

Shenzhen Yuanxing Pharmaceutical Co., Ltd

Tel: 0086-755-26740339

3. Device Information

Shenzhen Yuanxing Pharmaceutical Co., Ltd

Trade/Device Name	Agem ® Ag Mesh Dressing with Silver
Model & Specification	5cm ×5cm, 10cm×12cm, 10cm×20cm, 20cm×20cm
Common Name	Dressing with silver
Classification Name	Dressing, Wound, Drug
Regulatory Class	Unclassified
Unclassified Reason	Pre-Amendment
Classification regulation	Not applicable
Review Panel	General & Plastic Surgery
Product Code	FRO

4. Predicative Device

510(k) number	K053256
Trade/Proprietary name	3M™ Tegaderm™ Silver Nonwoven Dressing Also called 3M™ Tegaderm™ Ag Mesh Dressing with Silver
Sponsor	3M Health Care
Product Code	FRO
Regulatory Class	Unclassified
Classification regulation	Not applicable

5. Intended Use

Under the supervision of a health care professional, this dressing may be used as a primary wound dressing over:

- Abrasions
- Ulcers
- Trauma wounds
- Surgical wounds
- First and second degree burns
- Donor sites

This product is not designed, sold or intended for use except as indicated.

6. Device Description

Agem® Ag Mesh Dressing with Silver is a nonwoven dressing that contains (8mg/gm of dressing) of silver sulfate. The soft, absorbent dressing is supplied sterile and may be custom cut to fit the wound. The porous, non-occlusive dressing conforms to the wound

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base. The dressing creates an effective barrier and silver ions from the silver sulfate have been demonstrated in vitro to reduce the number of bacteria and yeast in the dressing.

7. Summary of non-clinical data

Non-clinical tests were conducted to verify that the proposed device met all design specification as was substantially equivalent(SE) to predicate device. Non-clinical test data was used to support the substantial equivalency.

7.1 Biocompatibility

Agem® Ag Mesh Dressing with Silver is identical to 3M™ Tegaderm™ Silver Nonwoven Dressing from 3M Health Care cleared in K053256, in material and physical proprieties and has the identical type and duration of patient contact.

A standard battery of biocompatibility studies was conducted:Cytotoxicity, Intracutaneous irritation in rabbits, and skin sensitization in Guinea Pig. No deleterious effects were observed with Agem® Ag Mesh Dressing with Silver.

They have the same biocompatibility performance and the equivalent safety in biocompatibility.

7.2 Performance testing

Agem® Ag Mesh Dressing with Silver has been evaluated for in in vitro reduction studies against a known number of microorganisms, such as gram negative and gram-positive bacteria and yeast and mold, the antibacterial effective barrier for seven days, silver sulfate, pH value, rate of moisture, fracture strength , absorbency, Minimum Effective Concentration (MEC) and silver release.

These characteristics, as well as the results of safety studies and effectiveness show the two products to be substantially equivalent.

8. Comparison to Predicate Device

The Agem® Ag Mesh Dressing with Silver submitted in this 510(k) file is substantially equivalent to the cleared 3M™ Tegaderm™ Silver Nonwoven Dressing which is the

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subject of K053256.

Item	Proposed Device	Predicate Device--K053256	S/D
Trade Name	Agem ® Ag Mesh Dressing with Silver	3M™ Tegaderm™ Silver Nonwoven Dressing	S
510(K) Number	----------	K053256	S
Classification Code	FRO	FRO	S
Indications for Use	is indicated for use as a primary wound dressing over: ● Abrasions ● Ulcers ● Trauma wounds ● Surgical wounds ● First and second degree burns ● Donor sites	is indicated for use as a primary wound dressing over: ● Abrasions ● Ulcers ● Trauma wounds ● Surgical wounds ● First and second degree burns ● Donor sites	S
Contraindications	should not be used on individuals that have a known hypersensitivity to silver or cotton. This product is not indicated for use as a surgical sponge or for use on third degree burns.	should not be used on individuals that have a known hypersensitivity to silver or cotton. This product is not indicated for use as a surgical sponge or for use on third degree burns.	S
silver sulfate	8 mg/g	8 mg/g	S
Antibacterial duration	7 days	7 days	S
Patient Contacting Material	cotton nonwoven	cotton nonwoven	S
Sterilization	^{60}Co Irradiation Sterilization	^{60}Co Irradiation Sterilization	S

Note: S/D : Same /Different

9. Conclusion

The results of the above comparison and discussion about the Agem® Ag Mesh Dressing

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with Silver demonstrate that the device is safe and effective as the legally marketed predicate devices.