K130117

# 510(k) Summary:

**Owner**:
Network Medical Products, Ltd.
Coronet House, Kearsley Road
Ripon, North Yorkshire
HG4 2SG, UK

**Phone**: (44) 01765 609555

**Submission contact:**
Alison March
Senior QA/RA Manager
Alison.M@networkmedical.co.uk
(44) 01765 609555

OCT 2 9 2013

**Date prepared:** October 27, 2013

**Device Common Name:** Ophthalmic Sponge

**Device Proprietary Name**: Network Eye Spears, Points, Drains, Wicks and Shields

**Classification**: Class II

**Regulation Number**: 886.4790

**Product Code**: HOZ

**Predicate Devices**:

Ultracell Medical Technologies, Inc., Ophthalmic Sponges, K920354
Ultracell Medical Technologies, Inc., Surgical Spears, K923922
DeRoyal Industries, Inc., Surgical Eye Spears, K972693
Hurricane Medical, Inc., Drainage Wick; Surgical Spears and Sponges, Corneal Light Shield, K990671

**Indication for Use:**

Eye Spears and Points: Indicated for all microsurgical ophthalmic procedures for tissue manipulation and management of fluids in the operative field.

Wicks and Drains: Indicated for all microsurgical ophthalmic procedures for management of fluids in the operative field.

Shields: Indicated for placement on the cornea to moisten the cornea and shield the retina from intense operating light during ophthalmic surgery.

**Description:**

Network Eye Spears, Points, Drains, Wicks and Shields are single use only, sterile devices designed for tissue manipulation, fluid management and shielding of light in ophthalmic surgery. Spears and points consist of a triangle of dry Polyvinyl Alcohol (formalized) Sponge (PVA) or Cellulose sponge, either attached to a polypropylene handle for handling or separate to be picked up by forceps. The triangular shape allows the surgeon to carry out pinpoint absorption of liquid. Drains and Wicks are PVA Sponges in various sizes and shapes for wicking of fluid away from the operative field. Shields are circular-shaped PVA Sponges that moisten the cornea and reduce the light intensity on the retina during surgery.

**Comparison to Predicate Devices:**

Network Eye Spears, Points, Drains, Wicks and Shields are equivalent to the predicates in intended use, design, and component materials as tabulated below.

**Comparison to Predicates:**

| Characteristics | Network Eye Spears, Points, Wicks, Drains and Shields<br>K130117 | Ultracell Eye Spears, Points, Wicks, Drains and Shields<br>K920354 &K923922 | DeRoyal Surgical Eye Spear<br>K972693 | Hurricane Medical Surgical Spears and Sponges, Corneal Light Shield, Drainage Wick<br>K990671 |
|---|---|---|---|---|
| **Indications for use** | Eye Spears and Points: Indicated for all microsurgical ophthalmic procedures for tissue manipulation and management of fluids in the operative field.<br>Wicks and Drains: Indicated for all microsurgical ophthalmic procedures for management of fluids in the operative field.<br>Shields: Indicated for placement on the cornea to moisten the cornea and shield the retina from intense operating light during ophthalmic surgery. | Fluid control and tissue manipulation of the surface of the eye during eye surgery. | Used to absorb fluids from the operative field during ophthalmic and microscopic surgical procedures. | Used to remove excess fluid and debris from the surgical area or instrument. Also, placed on the cornea to moisten the cornea and protect the retina from the intense operating light during ophthalmic surgery. |
| **Biocompatibility** | Acceptable results according to FDA Blue Book Memo, G95-1, on use of ISO 10993-1 tests. | Acceptable results according to FDA Blue Book Memo, G95-1, on use of ISO 10993-1 tests. | Acceptable results according to FDA Blue Book Memo, G95-1, on use of ISO 10993-1 tests. | Unknown |
| **Principles of operation** | Dry sponge wicking action removes fluid; triangular shape option allows for targeted absorption where needed; sponge shield is physical barrier for reduction of light. | Dry sponge wicking action removes fluid; triangular shape option allows for targeted absorption where needed; sponge shield is physical barrier for reduction of light. | Dry sponge wicking action removes fluid; triangular shape option allows for targeted absorption where needed. | Dry sponge wicking action removes fluid; triangular shape option allows for targeted absorption where needed; sponge shield is physical barrier for reduction of light. |
| **Sponge material** | Polyvinyl Alcohol (formalized) Sponge and Cellulose Sponges | Polyvinyl Alcohol (formalized) Sponge and Cellulose Sponges | Cellulose Sponge | Hydrocellulose, PVA Sponge, viscose and US-origin cotton |
| **Handle material, spears** | Polypropylene | Polypropylene | High density plastic | Plastic |
| **Sterility** | E-Beam Radiation, SAL $10^{-6}$; Sterile Barrier Packaging | E-beam Radiation, SAL $10^{-6}$; Sterile Barrier Packaging | EtO, SAL $10^{-6}$; Sterile Barrier Packaging | Gamma Radiation, SAL $10^{-6}$; Sterile Barrier Packaging |

## Non-clinical Testing:

Non-clinical testing for biocompatibility, sterility, and product/package stability was submitted to demonstrate substantial equivalence to the predicate devices, as detailed below. No clinical tests were submitted.

## 1. Biocompatibility

### PVA:

Biocompatibility tests recommended in ISO 10993 with the additional tests recommended in Blue Book Memo, G95-1, for evaluation of devices in contact with mucosal membranes or breached or compromised surfaces for a limited duration, were submitted for PVA Sponge and results found to be acceptable: Cytotoxicity, Sensitization, Primary Skin Irritation, Ocular Irritation, Acute Systemic Toxicity. Limulus Amebocyte Lysate (LAL, Gel Clot Method) testing to measure post-sterilization endotoxin demonstrates that NMP PVA Sponge devices are below the maximum specification limit of 20 EU/device. These biocompatibility tests demonstrate that NMP Polyvinyl Alcohol (formalized) Sponge devices are as safe as the predicate devices in that they are biocompatible for the intended use (as are the predicate devices).

### Cellulose:

Biocompatibility tests submitted for NMP Cellulose Sponge devices, together with the long history of safe clinical use of cellulose sponge, support the conclusion that NMP Cellulose Sponge devices do not produce adverse local or systemic effects when in limited duration contact with mucosal membranes or breached or compromised surfaces: Cytotoxicity, Sensitization. Limulus Amebocyte Lysate (LAL, Gel Clot Method) testing to measure post-sterilization endotoxin demonstrates that NMP Cellulose Sponge devices are below the maximum specification limit of 20 EU/device. These biocompatibility tests demonstrate that NMP Cellulose Sponge devices are as safe as the predicate devices in that they are biocompatible for the intended use (as are the predicates).

## 2. Sterility

Network ophthalmic sponge products will be sterilized with electron beam radiation to an SAL of $10^{-6}$. In accordance with the requirements of ISO 11137-1:2006 and ISO 11137-2:2012, a Method 1 sterilization validation supports the SAL of $10^{-6}$. These submitted results demonstrate that NMP Ophthalmic Sponge devices are as safe as the predicate devices in that they are sterilized by the same method (radiation) and to the same sterility assurance ($10^{-6}$) as predicate devices K920354, K923922 and K990671; and in the case of predicates K920354 &K923922, by the same radiation source (electron beam).

## 3. Product/Package Stability (Shelf Life)

Package integrity and product functionality testing performed on accelerated-aged product; manufactured, packaged and sterilized under normal production conditions; demonstrates that NMP Ophthalmic Sponge devices are functional for the defined shelf life of the product, and that product packaging provides a sterile barrier for the defined shelf life of the product. The shelf life testing submitted demonstrates that NMP Ophthalmic Sponge devices are as effective and perform as well as the predicate devices in that they are maintained as functional and in sterile condition by the sterile barrier packaging (as are the predicates).

# Conclusion:

Network Eye Spears, Points, Drains, Wicks and Shields are equivalent to the predicates in intended use, design, and component materials, and are identical in raw material and components to predicate devices K920354 &K923922. Non-clinical testing demonstrates that manufacturing processes undertaken by NMP produce substantially equivalent devices that are as safe, as effective, and perform as well as the predicates as follows:

- Biocompatibility tests demonstrate that NMP Ophthalmic Sponge devices are as safe as the predicate devices in that they are biocompatible for the intended use (as are the predicates).
- NMP Ophthalmic Sponge devices are as safe as the predicate devices in that they are sterilized by the same method (radiation) and to the same sterility assurance ($10^{-6}$) as predicate devices K920354, K923922 and K990671; and in the case of predicates K920354 &K923922, by the same radiation source (electron beam).
- Shelf life testing submitted demonstrates NMP Ophthalmic Sponge devices are as effective and perform as well as the predicate devices in that they are maintained as functional and sterile by the sterile barrier packaging (as are the predicates).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 29, 2013

Network Medical Products, Ltd
% Ms. Alison March
Senior QA/RA Manager
Coronet House, Kearsley Road
Ripon, North Yorkshire
HG4 2SG, United Kingdom

Re: K130117
Trade/Device Name: Network Eye Spears, Points, Drains, Wicks and Shield
Regulation Number: 21 CFR 886.4790
Regulation Name: Sponge, Ophthalmic
Regulatory Class: Class II
Product Code: HOZ
Dated: September 17, 2013
Received: September 17, 2013

Dear Ms. March:

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 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. 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,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

**510(k) Number**: K130117

**Device Name:** Network Eye Spears, Points, Wicks, Drains and Shields

**Indications for Use:**

Network Eye Spears and Points: Indicated for all microsurgical ophthalmic procedures for tissue manipulation and management of fluids in the operative field.

Network Wicks and Drains: Indicated for all microsurgical ophthalmic procedures for management of fluids in the operative field.

Network Shields: Indicated for placement on the cornea to moisten the cornea and shield the retina from intense operating light during ophthalmic surgery.

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 IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Leonid Livshitz -S
2013.10.23
'00'04'-14:24:33

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number:_____K130117____