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8. SECTION 8: 510(K) SUMMARY

8.1. Submitter and Contact Information

MAR 17

Submitter: Triosyn Corp.
1191 South Brownell Road
Williston, VT 05495

Contact: Kyle Anderson, Director of Life Science
Telephone: (802) 865-5084
Facsimile: (802) 658-2681
Email: kanderson@triosyn.com

8.2. Date of Preparation

June 8, 2005

8.3. Device Name

Trade Name:	Triosyn T40™ Antimicrobial Wound Dressing
Common Name:	Wound and Burn Dressing
Classification:	Unclassified

8.4. Legally Marketed Predicate Devices

Acticoat 7 Composite Wound Dressing (K001519)
Iodoflex Paste (K940414)

8.5. Device Description

The Triosyn T40™ Antimicrobial Wound Dressing is a sterile, primary wound dressing. It is a multi-layer composite dressing consisting of an absorbent polyester non-woven pad, a permeable adhesive, a single layer of Triosyn iodinated resin beads, and a non-adherent high-density polyethylene mesh (HDPE). This non-adhesive composite dressing is designed to be used as a barrier against microbial penetrations and as a method to reduce the microbial load in partial and full thickness wounds[7].

[7] Based on *in vitro* testing. Data on file.

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8.6. Intended Use

The Triosyn T40™ Antimicrobial Dressing provides an effective barrier to microbial penetration. The barrier function of the dressing may help reduce infection in partial and full thickness wounds, including:

- pressure ulcers
- venous ulcers
- diabetic ulcers
- first and second-degree burns
- donor sites
- surgical wounds

Triosyn Antimicrobial Dressings may be used over debrided and grafted partial thickness wounds.

8.7. Technological Characteristics

The differences between the subject device and predicate devices raise no new questions of safety and effectiveness.

8.8. Performance Information

The Triosyn T40™ Antimicrobial Wound Dressing was found in laboratory tests to be effective against a broad spectrum of clinically relevant microorganisms including gram-positive bacteria, gram-negative bacteria, and fungal organisms. This list includes multi-drug resistant organisms *Staphylococcus aureus* MRSA (ATCC 33591) and *Enterococcus faecalis* VRE (ATCC 51575).

In all instances, the Triosyn T40™ Antimicrobial Wound Dressing functioned as intended. The test results demonstrated that the Triosyn T40™ Antimicrobial Wound Dressing is both effective for its intended use and functions in a substantially equivalent manner to the predicate devices.

8.9. Biocompatibility

This product was tested in accordance with ISO 10993 requirements for biocompatibility using the following tests:

Cytotoxicity
Primary Skin Irritation
Closed Patch Sensitization

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8.10 Safety

The Triosyn T40™ Antimicrobial Wound Dressing was found in laboratory tests to consistently release less iodine in simulated wound exudates than a similarly sized Iodoflex dressing. The labeling for the Triosyn T40™ Antimicrobial Wound Dressing clearly identifies the product as containing iodine and warns that the dressing should not be used in patients with known or suspected iodine sensitivity or in patients with a history of a thyroid condition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2006

Triosyn Corp.
c/o Ms. Anne-Marie Gendron
Senior Director, Science & Project Management
1191 South Brownell Road
Willistown, Vermont 05495

Re: K051542
Trade/Device Name: Triosyn T40™ Antimicrobial Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 20, 2006
Received: February 22, 2006

Dear Ms. Gendron:

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 such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a

legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~K05142~~ K051542

Device Name: Triosyn T40™ Antimicrobial Dressing

Indications For Use:

The Triosyn T40™ Antimicrobial Dressing is designed for use in partial and full thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, first- and second-degree burns, donor sites and surgical wounds. The Triosyn T40™ Antimicrobial Dressing may be used over debrided and grafted partial thickness wounds.

Prescription Use __√__ 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 In Vitro Diagnostic Devices (OIVD)~~ Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K051542