9.5 510(k) Summary of Safety and Effectiveness

Collegium Pharmaceutical, Incorporated
Dryodine™ Antibacterial Gel
October 22, 2009

JUN 18 2010

9.5.1 Sponsor Name

Collegium Pharmaceutical, Incorporated
400 Highland Corporate Drive
Cumberland, RI 02864

Contact Individual:
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Director, Product Research & Development
Collegium Pharmaceutical, Inc.
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9.5.2 Device Name

Proprietary Name: Dryodine™ Antibacterial Gel
Common/Usual Name: Wound Dressing

9.5.3 Identification of Predicate or Legally Marketed Device

Dryodine™ Antibacterial Gel is substantially equivalent to the following predicate devices:

- Iodosorb Gel cleared under 510(k) K905069, from Perstorp Pharma.
- Triosyn T40 Antimicrobial Dressing under 510(k) K051452, from Triosyn Corporation

9.5.4 Device Description

Dryodine™ Antibacterial Gel consists of 0.1mm diameter biodegradable hydrophilic beads of cadexomer dispersed in a hydrophilic gel comprised of polyethylene glycol and poloxamer and contains 0.9% by weight iodine. The device is presented as a prescription product that requiring a physician to diagnosis the disease state and prescribe the product.

9.5.5 Intended Use

Dryodine™ Antibacterial Gel is indicated for use in the management/cleaning of wet ulcers and wounds such as venous stasis ulcers, pressure sores, diabetic foot ulcers, and traumatic and surgical wounds. Dryodine™ Antibacterial Gel assists to keep lesions soft and pliable.

9.5.6 Comparison of Technological Characteristics

Both the proposed Dryodine™ Antibacterial Gel and the predicate device Iodosorb Gel consist of 0.1mm diameter biodegradable hydrophilic beads of cadexomer dispersed in a hydrophilic Gel comprised of polyethylene glycol and poloxamer and contain 0.9% by weight iodine. Both the proposed and predicate devices are designed to be highly absorbent while providing a moist wound healing environment.

9.5.7 Performance Testing

In vitro effectiveness tests were conducted on Dryodine™ Antibacterial Gel.

9.5.8 Statement of Equivalency

Dryodine™ Antibacterial Gel is substantially equivalent in design, materials, construction and intended use to that of the predicate devices. The principal of operation of Dryodine™ Antibacterial Gel and the predicate devices is exactly the same. Since Dryodine™ Antibacterial Gel has the same intended use and technological characteristics as the predicate devices, Dryodine™ Antibacterial Gel does not raise any new safety and efficacy concerns when compared to the similar legally marketed devices. Testing and labeling demonstrate that Dryodine™ Antibacterial Gel is substantially equivalent to the predicate devices and is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUN 18 2010

Collegium Pharmaceutical Inc.
% Mark W. Trumbore, Ph.D.
Director, Product Research & Development
400 Highland Corporate Drive
Cumberland, Rhode Island 02864

Re: K093320
Trade/Device Name: Dryodine™ Antibacterial Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 14, 2010
Received: May 17, 2010

Dear Dr. Trumbore:

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 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" (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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1 **SUBSECTION 1.8**

GENERAL INFORMATION **Statement of Indications for Use**

1.7 Statement of Indications for Use

510(k) Number (if known): K093320

Device Name: Dryodine™ Antibacterial Gel

Indications For Use:

Dryodine™ Antibacterial Gel is indicated for use in the management/cleaning of wet ulcers and wounds such as venous stasis ulcers, pressure sores, diabetic foot ulcers, and traumatic and surgical wounds. Dryodine™ Antibacterial Gel assists to keep lesions soft and pliable.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093320