Innocoll
Pharmaceuticals

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510(k) Summary

1. **Date Prepared:** **September 9th , 2010**

2. **Submitter**

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Submission Correspondent:

Aaron Wyse
Director of Regulatory Affairs

3. **Proprietary Name:** Collexa

4. **Common Name:** Topical Wound Dressing

5. **Device Classification:** Product Code: KGN
Classification Name: Dressing Wound Collagen
Regulatory Class: Unclassified

6. **Statement of Substantial Equivalence:**

Collexa is substantially equivalent in materials of construction and intended use to Collatek Foam (K012997) and Collagen Sponge (K092805).

7. Intended Use

Collexa may be used for the management of wounds such as:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular etiologies
- Full-thickness & partial thickness wounds
- Abrasions
- Traumatic wounds
- 1st and 2nd degree burns
- Dehisced surgical wounds
- Exuding wounds

8. Description

Collexa is a collagen matrix sponge with a polyurethane foam backing intended for topical use on wounds as described in the intended use section of this 510(k) summary. The polyurethane foam is absorbent and acts as a reservoir for wound exudates. The product is supplied sterile for single use only.

9. Biocompatibility

Biocompatibility testing has confirmed that Collexa meets all the biocompatibility testing requirements in accordance with ISO 10993-1:2009. Biocompatibility data demonstrates that Collexa is safe for use as a wound management device.

10. Conclusion

Collexa is substantially equivalent to the predicate devices delineated in this submission and meets the requirements for premarket notification as defined in CFR21, Part 807.

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

Innocoll Pharmaceuticals
% Mr. Aaron Wyse
Director of Regulatory Affairs
Midlands Innovation and Research Centre
Dublin Road, Athlone
Co. Westmeath, Ireland

OCT 2 8 2010

Re: K100574
Trade/Device Name: Collexa
Regulatory Class: Unclassified
Product Code: KGN
Dated: October 01, 2010
Received: October 04, 2010

Dear Mr. Wyse:

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

Statement of Indications for Use

510(k) Number (if known): K100574

OCT 2 8 2010

Device Name: Collexa

Indications For Use:

Indications:
Collexa may be used for the management of wounds including:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular etiologies
- Full-thickness & partial thickness wounds
- Abrasions
- Traumatic wounds
- 1st and 2nd degree burns
- Dehisced surgical wounds
- Exuding wounds

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)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Concurrence of CDRH, Office of Device Evaluation (ODE) 510(k) Number K100574