K110388

AUG -9 2011

Innocoll
Pharmaceuticals

Midlands Innovation and Research Centre
Dublin Road,
Athlone, Co. Westmeath, Ireland
Tel: + 353 (0)90 6486834
Fax: + 353 (0)90 6486835
www.innocoll-pharma.com

510(k) Summary

Date Prepared: 27th June 2011

Submitter:
Innocoll Pharmaceuticals,
Midland Innovation and Research Centre,
Dublin Road,
Athlone,
Co. Westmeath,
Ireland.

Submission Correspondent:
Aaron Wyse
Director of Regulatory Affairs
Tel: +353 (0) 9066 90661
Fax: +353 (0) 9066 34895

Proprietary Name: Collacare Dental

Common Name: Collagen dental matrix

Device Classification:

Product Code:	KGN
Classification Name:	Wound Dressing, Collagen
Regulatory Class:	Unclassified

Statement of Substantial Equivalence:
Collacare Dental is substantially equivalent in materials of construction to Collagen Sponge (K092805), Collagen Wound dressing – Oral (K040403), Salicept Oral Patch (K012126) is a hydrogel containing non-collagen materials.

K110388

Intended Use:
Collacare Dental is indicated for the management of oral wounds and sores, including:

- denture sores
- oral ulcers (non-infected or viral)
- periodontal surgical wounds
- suture sites
- burns
- surgical wounds and traumatic wounds

Description:
Collacare Dental is a conformable collagen matrix manufactured from purified type I collagen derived from bovine Achilles tendon. Collacare Dental is supplied sterile and non-pyrogenic, in various sizes, and for single use only.

Biocompatibility:
There are no new biocompatibility issues arising with the use of Collacare Dental as the materials of construction and finished product material match that of Collagen Sponge (K092805). A complete biocompatibility evaluation was undertaken in line with the requirements of ISO 10993-1.

Conclusion:
Collacare Dental 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

Mr. Aaron Wyse
Director of Regulatory Affairs
Innocoll Pharmaceuticals, Limited
Midland Innovation and Research Centre,
Dublin Road,
Athlone, Co. Westmeath,
IRELAND

AUG - 9 2011

Re: K110388
Trade/Device Name: Collacare Dental
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 25, 2011
Received: July 28, 2011

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 110388

Statement of Indications for Use

510(k) Number (if known):

Device Name: Collacare Dental

Indications For Use:

Collacare Dental is indicated for the management of oral wounds and sores, including:

- denture sores
- oral ulcers (non-infected or viral)
- periodontal surgical wounds
- suture sites
- burns
- surgical wounds and traumatic 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number K110388