

K103648

SEP 14 2011

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# 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:** September 13<sup>th</sup> 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) 87 0520845  
Fax: +353 (0) 9066 34895

**Proprietary Name:** Collagen Powder

**Common Name:** Topical Wound Dressing

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

### **Statement of Substantial Equivalence:**

Collagen Powder is substantially equivalent in materials of construction and intended use to Collagen Sponge (K092805) and Collatek Powder (K012990). Collagen Powder has been evaluated for its biocompatibility which meets requirements and is therefore substantially equivalent to the predicates delineated in this submission. Collagen Powder is manufactured from the same ingredients used for the manufacture of Collagen Sponge (K092805).

Collagen Powder 510k  
510k Summary

K103648

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**Intended Use:**

Collagen Powder may be used for the management of wounds such as:

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

**Description:**

Collagen Powder is a collagen matrix in powder form intended for application as a wound management device. The product is supplied sterile for single use only.

**Biocompatibility and Testing:**

Evaluation of the biocompatibility of Collagen Powder was completed in line with the requirements of ISO 10993 -1: 2009. There are no new biocompatibility issues arising with the use of Collagen Powder; the materials of construction for Collagen Powder match Collagen Sponge (K092805).

Biochemical characterization of the collagen used to manufacture Collagen Powder was undertaken which characterized the collagen as being predominantly Type I collagen which is not denatured during the collagen rendering process.

Viral inactivation validation assessment was conducted on the collagen which demonstrates that the collagen material post processing can be assumed not to contain any pathogenic organisms.

Particle size analysis was conducted on the finished product which verified a particle size range for Collagen Powder.

**Conclusion:**

Collagen Powder 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, Ltd.  
% Mr. Aaron Wyse  
Directory of Regulatory Affairs  
Midlands Innovation & Research Centre, Dublin Road  
Athlone, Co. Westmeath  
Ireland

Re: K103648  
Trade/Device Name: Collagen Powder  
Regulatory Class: Unclassified  
Product Code: KGN  
Dated: September 1, 2011  
Received: September 6, 2011

SEP 14 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

Page 2 - Mr. Aaron Wyse

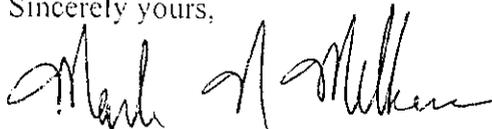
CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control 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" (21 CFR 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

K103 648

**Statement of Indications for Use**

510(k) Number (if known):

Device Name: Collagen Powder

Indications For Use: Collagen Powder may be used for the management of wounds such as:

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

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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)

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

K103 648

510(k) Number \_\_\_\_\_



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -W066-G609  
Silver Spring, MD 20993-0002

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

Re: K103648

Trade/Device Name: Collagen Powder  
Regulatory Class: Unclassified  
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Dated: September 1, 2011  
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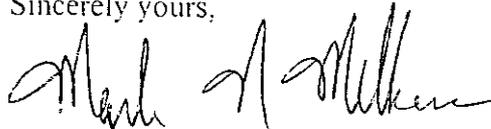
Page 2 - Mr. Aaron Wyse

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Sincerely yours,



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

Enclosure

K103 648

Statement of Indications for Use

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- o Abrasions
- o Traumatic wounds
- o 1st and 2nd degree burns
- o Dehisced surgical wounds
- o Exuding wounds

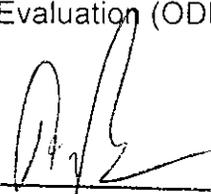
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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)



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

510(k) Number

K103 648



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

## Public Health Service

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Control Center WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20993-0002

September 07, 2011

INNOCOLL PHARMACEUTICALS LTD  
 MIDLANDS RESEARCH AND  
 INNOVATION CENTRE, DUBLIN RD.  
 ATHLONE, CO. WESTMEATH  
 IRELAND EI  
 ATTN: AARON WYSE

510k Number: K103648

Product: COLLAGEN POWDER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

March 10, 2011

510k Number: K103648

Product: COLLAGEN POWDER

Extended Until: 08/24/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health

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# Innocoll Pharmaceuticals

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

FDA CDRH DMC

MAR 10 2011

Received

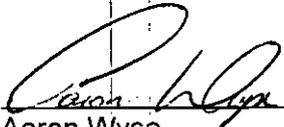
K42

510(k) Number: K103648  
Product Name: Collagen Powder  
Date: March 2<sup>nd</sup> 2011

Dear Sir/Madam,

We would like to request an extension of time to respond to the additional information requested for 510(k) K103648 for Collagen Powder. We would like the time extension of the maximum 180 days to be applied to our file as we work through providing the additional information.

Kind Regards



Aaron Wyse  
Director of Regulatory Affairs  
Innocoll Pharmaceuticals Ltd.

Date: 2<sup>nd</sup> March 2011



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Control Center WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20993-0002

February 25, 2011

510k Number: K103648

Product: COLLAGEN POWDER

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission **MUST** cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm138935.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 10k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

## Public Health Service

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Control Center WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20993-0002

February 25, 2011

510k Number: K103648

Product: COLLAGEN POWDER

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission **MUST** cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

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If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm090351.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

## Public Health Service

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Mail Center 4 WO66-G609  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20993-0002

December 16, 2010

INNOCOLL PHARMACEUTICALS LTD  
 MIDLANDS RESEARCH AND INNOVATIONCENTRE, DUBLIN RD.  
 ATHLONE  
 IRELAND  
 ATTN: AARON WYSE

510k Number: K103648

Received: 12/14/2010

Product: COLLAGEN POWDER

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

64

K103648

# Innocoll Pharmaceuticals

Midlands Innovation & Research Centre  
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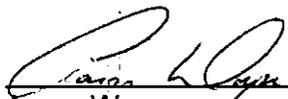
FDA  
DEC  
4 2010  
Received

Product Name: Collexa  
Date: 9<sup>th</sup> December 2010

Dear Sir/Madam,

Please find enclosed the 510(k) premarket notification application for Collagen Powder. Duplicate hard copies of the application file are enclosed as is mandatory. Also enclosed please find one electronic copy. The electronic copy is a replicate of the hard copies in all sections with the exception of sections 17 and 18. Sections 17 and 18 have not been included in the electronic copy as these sections comprise FDA electronic forms which cannot be saved electronically but merely printed in hard copy. The electronic copy is available on the inner leaf of one of the hard copy files,

Kind Regards



Aaron Wyse  
Director of Regulatory Affairs  
Innocoll Pharmaceuticals Ltd.

Date: 9<sup>th</sup> Dec 2010

K25

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Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statem

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	PAYMENT IDENTIFICATION NUMBER: <b>b4</b> Write the Payment Identification number on your check.
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A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/mdufma/cover sheet.html>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  INNOCOLL PHARMACEUTICALS Midlands Innovation and Research Centre Athlone IE  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Aaron Wyse 2.1 E-MAIL ADDRESS awyse@innocoll-pharma.com 2.2 TELEPHONE NUMBER (include Area code) 353906486280 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
---	--

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/oc/mdufma>)

Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
---	--

K25

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA       NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 90 days of FDA's approval/clearance of this device.)

NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <http://www.fda.gov/cdrh/mdufma> for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

This application is the first PMA submitted by a qualified small business, including any affiliates       The sole purpose of the application is to support conditions of use for a pediatric population

This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only       The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES       NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

**b4** 29-Nov-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

*[Handwritten signatures]*  
29th Nov 2010

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>CDRH PREMARKET REVIEW SUBMISSION COVER SHEET</b>	Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.
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Date of Submission 11-18-2010	User Fee Payment ID Number N/A	FDA Submission Document Number (if known) N/A
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**SECTION A TYPE OF SUBMISSION**

<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission?  Yes  No (If Yes, please complete Section I, Page 5)

**SECTION B SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name Innocoll Pharmaceuticals Ltd.	Establishment Registration Number (if known) N/A		
Division Name (if applicable) N/A	Phone Number (including area code) +353 (0)90 66 66091		
Street Address Midlands Research and Innovation Centre, Dublin Road.	FAX Number (including area code) +353 (0)90 66 34895		
City Athlone	State / Province Co. Westmeath	ZIP/Postal Code N/A	Country Ireland
Contact Name Sharon Wyse			
Contact Title Director of Regulatory Affairs		Contact E-mail Address awyse@Innocoll-pharma.com	

**SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ( )	
Street Address		FAX Number (including area code) ( )	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

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SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (specify):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final					
<input type="checkbox"/> Other Reason (specify):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason (specify):					

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**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	KGN	2		3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K092805	2	Collagen Sponge	2	Syntacoll GmbH
2	K012990	3	Collatek Powder	3	Collatek
3					
4		4		4	
5		5		5	
6		6		6	

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification  
 Dressing, Wound, Collagen

	Trade or Proprietary or Model Name for This Device		Model Number
1	Collagen Powder	1	N/A
2		2	
3		3	
		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome) N/A

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission  
 Laboratory Testing     Animal Trials     Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code KGN	C.F.R. Section (if applicable) N/A	Device Class <input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input checked="" type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)  
 Collagen Powder may be used for the management of wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, ulcers caused by mixed vascularities, full-thickness and partial thickness wounds, abrasions, traumatic wounds, 1st and 2nd degree burns, dehisced surgical wounds and exuding wounds.

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 3005433617	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Syntacoll GmbH		Establishment Registration Number 3005433617		
Division Name (if applicable) N/A		Phone Number (including area code) +49 (0)9441 68600		
Street Address Industriegebiet Saal, Donaustraße 24		FAX Number (including area code) +49 (0)9441 686030		
City Saal / Donau		State / Province	ZIP/Postal Code 93342	Country Germany
Contact Name Dr. Alexandra Dietrich		Contact Title Managing Director		Contact E-mail Address <a href="mailto:adietrich@syntacoll.de">adietrich@syntacoll.de</a>

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number N/A	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name b4		Establishment Registration Number b4		
Division Name (if applicable) b4		Phone Number (including area code) b4		
Street Address b4		FAX Number (including area code) b4		
City b4		State / Province	ZIP/Postal Code b4	Country Germany
Contact Name b4		Contact Title b4		Contact E-mail Address b4

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City		State / Province	ZIP/Postal Code	Country
Contact Name		Contact Title		Contact E-mail Address

## SECTION I

## UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 22442-1	Adopted European Standard	MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 1: APPLICATION OF RISK MANAGEMENT	First	2007
2	ISO 22442-2	Adopted European Standard	MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 2: CONTROLS ON SOURCING, COLLECTION AND HANDLING	First	2007
3	ISO 22442-3	Adopted European Standard	MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 3: VALIDATION OF THE ELIMINATION AND/OR INACTIVATION OF VIRUSES AND TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) AGENTS	First	2007
4	ISO 10993-1	ISO	BIOLOGICAL EVALUATION OF MEDICAL DEVICES - EVALUATION AND TESTING	Third	2003
5	ISO-11137-1	ISO	STERILIZATION OF HEALTH CARE PRODUCTS - RADIATION - PART 1: REQUIREMENTS FOR DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES	Latest Version	2006
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration  
CDRH (HFZ-342)  
9200 Corporate Blvd.  
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

**510(k) Notification**

**Date:** 08th November 2010

**Address:** Innocoll Pharmaceuticals,  
IDA Business Park,  
Castlerea Road, Gallowstown,  
Roscommon Town,  
Co. Roscommon,  
Ireland.

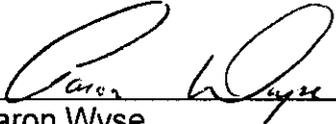
**Correspondent:** Aaron Wyse

**Contact Numbers:** Tel: +353 (0) 9066 66091  
Fax: +353 (0) 9066 34895

**Manufacturing Sites:** Syntacoll GmbH,  
Industriegebiet Saal,  
Donaustraße 24,  
93342 Saal/Donau,  
Germany.

**Sterilisation Site:** Isotron Deutschland GmbH,  
Kesselbodenstrasse 7,  
85391 Allershausen,  
Germany.

**Signed:**

  
\_\_\_\_\_  
Aaron Wyse  
Director of Regulatory Affairs

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**Statement of Indications for Use**

510(k) Number (if known):

Device Name: Collagen Powder

Indications For Use: Collagen Powder may be used for the management of wounds such as:

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

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# Innocoll Pharmaceuticals

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Athlone, Co. Westmeath, Ireland  
Tel: + 353 (0)90 6486834  
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## 510(k) Summary

**Date Prepared:** November 08th 2010  
**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:** Collagen Powder

**Common Name:** Topical Wound Dressing

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

### **Statement of Substantial Equivalence:**

Collagen Powder is substantially equivalent in materials of construction and intended use to Collagen Sponge (K092805) and Collatek Powder (K012990).

**Intended Use:**

Collagen Powder 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

**Description:**

Collagen Powder is a collagen matrix in powder form intended for application as a wound management device. The product is supplied sterile for single use only.

**Biocompatibility:**

There are no new biocompatibility issues arising with the use of Collagen Powder as the materials of construction and finished product material match that of Collagen Sponge (K092805).

**Conclusion:**

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

# Innocoll Pharmaceuticals

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## PREMARKET NOTIFICATION

### TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Director of Regulatory Affairs of Innocoll Pharmaceuticals, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

  
(Signature)

Aaron Wyse  
(Typed Name)

30<sup>th</sup> Nov 2010  
(Date)

\_\_\_\_\_  
\*(Premarket Notification [510(k)] Number)

# Innocoll Pharmaceuticals

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Tel: + 353 (0)90 6486834  
Fax: + 353 (0)90 6486835  
www.innocoll-pharma.com

## Device Classification, Trade Name and Establishment Registration for Collagen Powder

Proprietary Name: Collagen Powder

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

Establishment Registration: Syntacoll GmbH  
Establishment Registration #3005433617



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Aaron Wyse  
Director of Regulatory Affairs

30<sup>th</sup> Nov 2010  
Date





Collagen Powder 510k  
Substantial Equivalence Table

Feature	Collagen Powder	Collagen Sponge	Collatek Powder
<b>Manufacturer</b>	Syntacoll GmbH	Syntacoll GmbH	BioCore Medical Technologies
<b>Indications for Use</b>	<p>Collagen Sponge may be used for the management of wounds such as:</p> <ul style="list-style-type: none"> <li>• Pressure ulcers</li> <li>• Venous ulcers</li> <li>• Diabetic ulcers</li> <li>• First and second degree burns</li> <li>• Ulcers caused by mixed vascular etiologies</li> <li>• Partial and full-thickness wounds</li> <li>• Abrasions</li> <li>• Traumatic wounds</li> <li>• Dehisced surgical wounds</li> <li>• Exuding wounds</li> </ul>	<p>Collagen Sponge may be used for the management of wounds such as:</p> <ul style="list-style-type: none"> <li>• Pressure ulcers</li> <li>• Venous stasis ulcers</li> <li>• Diabetic ulcers</li> <li>• First and second degree burns</li> <li>• Partial and full thickness wounds</li> <li>• Superficial injuries</li> </ul>	<p>Collatek® Powder may be used for the management of wounds such as:</p> <ul style="list-style-type: none"> <li>• Pressure ulcers</li> <li>• Venous ulcers</li> <li>• Diabetic ulcers</li> <li>• First and second degree burns</li> <li>• Ulcers caused by mixed vascular etiologies</li> <li>• Dermal lesions and injuries</li> </ul>
<b>Materials</b>	Bovine tendon collagen matrix	Bovine tendon collagen matrix	Bovine tendon collagen matrix
<b>Collagen Source</b>	Bovine tendon	Bovine tendon	Bovine hide
<b>Biodegradable</b>	Yes	Yes	Yes
<b>Biocompatible</b>	Yes	Yes	Yes
<b>Non- Pyrogenic</b>	Yes	Not claimed	Not claimed
<b>Sterile</b>	Yes - Gamma irradiation	Yes - Gamma irradiation	Yes - E-beam irradiation
<b>Sizes</b>	0.5 and 1 g tube	70 and 280 mg sponges	1 g sachet
<b>Storage Conditions</b>	Room temperature less than 25°C	Room temperature less than 25°C	Store in a cool dry place
<b>Target Population</b>	Can be used on patients of all ages who require wound management products	Can be used on patients of all ages who require wound management products	Can be used on patients of all ages who require wound management products
<b>Design</b>	Powdered Type I bovine collagen matrix	Type I bovine collagen sponge	Powdered Type I bovine collagen matrix
<b>Performance</b>	As per indications	As per indications	As per indications
<b>Anatomical Sites</b>	The device is for topical use on wounds and is not restricted for use in any anatomical site	The device is for topical use on wounds and is not restricted for use in any anatomical site	The device is for topical use on wounds and is not restricted for use in any anatomical site
<b>Mechanical Safety</b>	There are no mechanical parts on this device	There are no mechanical parts on this device	There are no mechanical parts on this device

30<sup>th</sup> Nov 2014

Date:

Completed by: 

Collagen Powder 510k  
Substantial Equivalence Table

Feature	Collagen Powder	Collagen Sponge	Collatek Powder
<b>Chemical Safety</b>	The device does not chemically react with the patient when applied	The device does not chemically react with the patient when applied	The device does not chemically react with the patient when applied
<b>Electrical Safety</b>	The device does not supply or deliver electrical energy and is not used in conjunction with devices which supply or deliver electrical energy	The device does not supply or deliver electrical energy and is not used in conjunction with devices which supply or deliver electrical energy	The device does not supply or deliver electrical energy and is not used in conjunction with devices which supply or deliver electrical energy
<b>Thermal Safety</b>	The device does not generate deliver or extract heat when in use	The device does not generate deliver or extract heat when in use	The device does not generate deliver or extract heat when in use
<b>Radiation Safety</b>	The device does not generate or deliver any radiation when in use	The device does not generate or deliver any radiation when in use	The device does not generate or deliver any radiation when in use
<b>Human Factors</b>	<p>Contra-indications: Refer to Instructions Leaflet.</p> <p>Collagen Powder should not be used in cases of known allergy to cattle proteins.</p> <p>Collagen Powder has no antibacterial effect and must not be used in infected areas.</p> <p>Precautions: discontinue use of Collagen Powder and notify your doctor if excessive redness, pain, swelling or blistering occurs.</p> <p>Collagen Powder is not indicated for use on for third-degree burns.</p>	<p>Contra-indications: Refer to Instructions Leaflet.</p> <p>Collagen Sponge should not be used in cases of known allergy to cattle proteins.</p> <p>Collagen Sponge has no antibacterial effect and must not be used in infected areas.</p> <p>Precautions: discontinue use of Collagen Sponge and notify your doctor if excessive redness, pain, swelling or blistering occurs.</p>	<p>Do not use if you have an allergy to bovine derived materials</p>
<b>Energy Used and or Delivered</b>	This device does not supply or deliver electrical energy	This device does not supply or deliver electrical energy	This device does not supply or deliver electrical energy
<b>Where Used</b>	General hospital and personal use	General hospital and personal use	General hospital and personal use
<b>Standards Met</b>	EN ISO 12442-1:2007; EN ISO 12442-2:2007; EN ISO 12442-3:2007 ISO 10993-1:2009; ISO 11137-1:2006	EN ISO 12442-1:2007; EN ISO 12442-2:2007; EN ISO 12442-3:2007 ISO 10993-1:2009; ISO 11137-1:2006	Unavailable

Completed by: *C. P. Payne* Date: 30<sup>th</sup> Nov 2010

## Discussion: Substantial Equivalence for Collagen Powder

**Biocompatibility:** Collagen Powder is made from the same material as Collagen Sponge (K092805). Additionally, Collatek® Powder (K012990) is biocompatible and approved for marketing in the US since 2002. Collagen Powder is fully biocompatible as demonstrated by the test reports included in Section 12 of this premarket notification file.

**Sterility:** Collagen Powder is supplied sterile - the method of sterilization used is gamma radiation. Collagen Sponge uses gamma radiation as the method of sterilisation. The method of sterilisation used for Collatek® Powder is e-beam radiation.

**Sizes:** Collagen Powder is presented in two sizes 0.5 g and 1 g and can be used for any wound size. Collagen Sponge is presented in two sizes (5cm x 5cm and 10cm x 10cm and can be cut to fit wound size). Collatek® Powder is available in 1 g units.

**Storage Conditions:** Collagen Powder should be stored at room temperature up to 25°C/77°F. Details of the storage conditions are presented on the product labelling. Storage conditions are the same as those detailed for the Collagen Sponge. Collatek® Powder instructions define storage to be in a cool dry place.

**Target Population:** There is no target population for any of the three devices described. The devices are indicated for wound management, which is the target condition and not specific to a particular target population.

**Design:** The devices are produced as powders or sheet (which can be cut to size and shape) to fit a wound. The devices are designed to manage specific wound types as defined by the indications for each product.

**Performance:** The devices are used for the management of various wound types. The devices (Collagen Powder and Collatek® Powder) act in the same manner and have the same type of application as detailed in the instructions for use. The Collagen Sponge is manufactured using the same collagen as that used to manufacture the Collagen Powder. This device acts as a wound management device in the same manner as the Collagen Powder and Collatek® Powder.

**Anatomical Sites:** The devices (Collagen Powder, Collatek® Powder and Collagen Sponge) are for topical use on breached dermis. There is no anatomical restriction beyond this for the use of any of the devices.

**Mechanical Safety:** N/A, refer to Substantial Equivalence Table.

**Chemical Safety:** N/A, refer to Substantial Equivalence Table.

**Electrical Safety:** N/A, refer to Substantial Equivalence Table.

**Thermal Safety:** N/A, refer to Substantial Equivalence Table.

**Radiation Safety:** N/A, refer to Substantial Equivalence Table.

**Human Factors:** As detailed in the Substantial Equivalence Table, the precautions and contraindications for Collagen Powder are presented below:

**Precautions**

Collagen Powder should not be used when visible signs of infection are present in the wound area.

Discontinue the use of Collagen Powder and notify your doctor if excessive redness, pain, swelling or blistering occurs.

**Contraindications**

Collagen Powder is not indicated for use on for third-degree burns. Collagen Powder should not be used on patients with known sensitivity or allergy to animal proteins.

As detailed above there are certain human factors which affect the use of the device.

**Energy Use and Delivered:** N/A, refer to Substantial Equivalence Table.

**Where Used:** Collatek® Powder and Collagen Sponge are approved in the US as topical collagen wound dressings under product code KGN "Wound Dressing Collagen". Collagen Powder and both predicate devices are indicated for wound management.

**Standards Met:** Collagen Powder has been assessed and meets the requirements of the following standards:

ISO 22442-1: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 1: APPLICATION OF RISK MANAGEMENT
ISO 22442-2: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 2: CONTROLS ON SOURCING, COLLECTION AND HANDLING
ISO 22442-3: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 3: VALIDATION OF THE ELIMINATION AND/OR INACTIVATION OF VIRUSES AND TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) AGENTS
ISO 10993-1:2009 BIOLOGICAL EVALUATION OF MEDICAL DEVICES – EVALUATION AND TESTING WITHIN A RISK MANAGEMENT PROCESS
ISO 11137 -1: 2006 STERILIZATION OF HEALTH CARE PRODUCTS - RADIATION - PART 1: REQUIREMENTS FOR DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES.

Meeting the requirements of these standards ensures the product is safe for human use. The standards met by Collagen Sponge are detailed in the substantial equivalence table. The standards met information for Collatek® Powder is not available.

### **510(k) Substantial Equivalence Decision-Making Process**

Following the FDA's 510(k) decision making process flow chart (Figure 1, overleaf), the following can be concluded:

*New device is compared to a marketed device?*

Yes, Collagen Powder is comparable to the marketed devices (Collatek® Powder and Collagen Sponge). Both Collagen Powder and Collatek® Powder are comprised of bovine collagen and have the same indications and intended use.

*Does the new device have the same indication statement?*

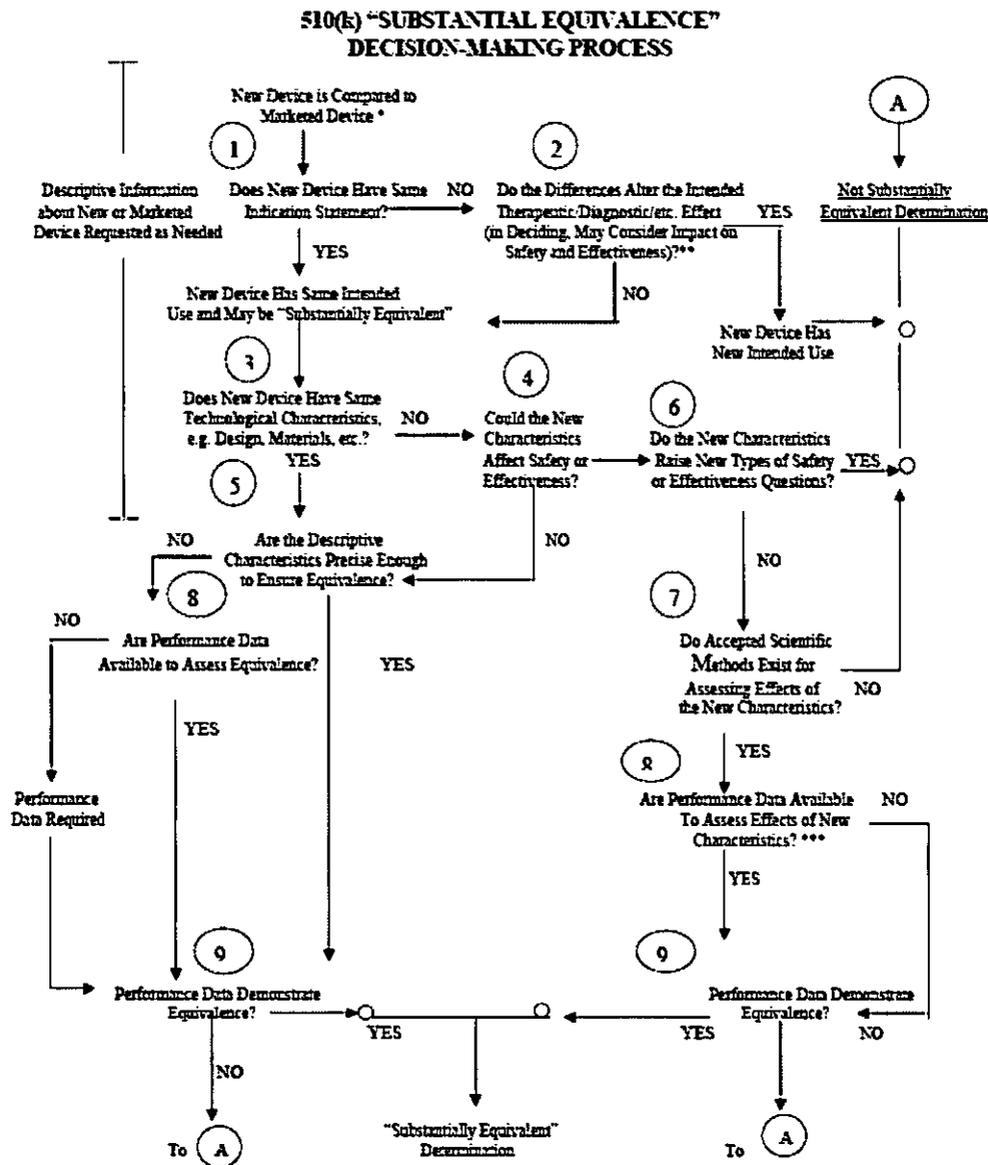
The indication statement for Collagen Powder includes those stated for Collagen Sponge and Collatek® Powder and includes the management of the additional wound types: ulcers caused by mixed vascular etiologies, abrasions, traumatic wounds, dehisced surgical wounds and exuding wounds.

*Does the new device have the same technological characteristics e.g. design materials etc?*

Yes, Collagen Powder and Collatek® Powder have the same technological characteristics in terms of materials and design. Both products are made using purified Type I bovine collagen. The collagen sponge has the same technological

characteristics in terms of materials, being made using purified Type I bovine collagen.

Figure 1: 510(k) Substantial Equivalence Decision-Making Process



- \* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- \*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- \*\*\* Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

*Are the descriptive characteristics precise enough to ensure equivalence?*

The descriptive characteristics of both Collagen Powder and Collatek® Powder indicate that the devices are substantially equivalent in terms of indications for use, materials, design and technological characteristics. The Collagen Sponge is substantially equivalent in terms of indications for use, materials and technological characteristics. All devices are fully biocompatible and in terms of safety for the user are substantially equivalent.

**Conclusion:**

The above discussion in combination with the details outlined in the Substantial Equivalence Table for Collagen Powder, Collatek® Powder and Collagen Sponge indicates that Collagen Powder is substantially equivalent to both Collatek® Powder and Collagen Sponge.

Completed By:



Date:

30<sup>th</sup> Nov 2010

FEB. 17. 2010 11:15AM

NO. 0966 P. 1/3



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

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

FEB 16 2010

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

Re: K092805  
 Trade/Device Name: Collagen Sponge  
 Regulatory Class: Unclassified  
 Product Code: KGN  
 Dated: January 27, 2010  
 Received: February 2, 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

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Page 2 - Mr. Aaron Wyse

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" (21 CFR 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

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FEB. 17. 2010 11:16AM

NO. 0966 P. 3/3

*K092805*

**Statement of Indications for Use**

510(k) Number (if known): \_\_\_\_\_

Device Name: Collagen Sponge

Indications For Use:

**Indications:**

Collagen Sponge may be used for the management of wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- First and second degree burns
- Partial and full thickness wounds
- Superficial injuries

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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)

*Mark A. Wilson*

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

510(k) Number           K092805          

09 000010

92

OCT 24 2001

K012990

1/3

**BioCore Medical Technologies, Inc.**

*State-of-the-Art Biomaterials Technologists*

Phone: 888-565-5243  
301-625-6818  
Fax: 301-625-6819

11800 Tech Road; Suite #240  
Silver Spring, Maryland 20904  
U.S.A.

**510(k) Summary**

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92"

"The assigned 510(k) number is: K012990"

**Submitter's Name and Address:**

BioCore Medical Technologies, Inc.  
11800 Tech Rd. Suite 240  
Silver Spring, MD 20904

**Contact Person, Telephone and Fax Number:**

Ajay Kumar, VP of Operations  
Phone: (301) 625-6818  
Fax: (301) 625-6819

**Date the Summary was Prepared:**

September 19, 2001

**Device Names:**

Proprietary Name: Collatek® Powder  
Common Name: hydrocolloid wound powder  
Classification Name: wound and burn dressing

**Predicate Device:**

Trade name: hyCURE® Powder  
Company: Hymed Group Corporation  
  
Trade name: Comfeel® Powder  
Company: Coloplast Group, Ltd.  
  
Trade name: Medifil® Particles  
Company: BioCore Medical Technologies, Inc.

*Collagen*

BioCore Medical Technologies, Inc.  
Collatek Powder

Traditional 510(k)

E-1

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**Device Description:**

Collatek® Powder is a sterile, disposable, single use, wound-dressing device for the management of dermal lesions and injuries. It is to be used to fill in full and partial thickness wounds with moderate to heavy exudate. Collatek® Powder is able to conform to any wound site.

Collatek® Powder is a hydrophilic, hydrocolloid wound-powder with a collagen base. Collatek® Powder's collagen is an insoluble fibrous type I bovine collagen derived from cowhide. Collatek® Powder will be available in a 1 gram size packet, additional sizes may be introduced at a later time

**Basis for Substantial Equivalence:***1. Indications for Use*

Collatek® Powder will be used to manage full thickness and partial thickness wounds with moderate to heavy exudate. Collatek® Powder is intended for use on: pressure ulcers (stages I-IV), venous ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, first and second degree burns, donor sites and other bleeding or secreting dermal lesions and injuries.

Collatek® Powder's indications for use are comparable to the commercially available predicate devices (hyCURE® Powder, Comfeel® Powder and Medifil® II Particles).

*2. Instructions for Use*

Collatek® Powder's manner of use is similar to other wound care products. First, cleanse the wound. Second, apply medication to wound as indicated. Third, apply Collatek® Powder to the wound surface. Lastly, Cover with absorbent dressing and change dressing as needed in accordance with labeling instructions.

Collatek® Powder's instructions for use are comparable to the commercially available predicate devices (hyCURE® Powder, Comfeel® Powder and Medifil® II Particles).

*3. Technological Characteristics*

BioCore Medical Technologies, Inc.  
Collatek Powder

Traditional 510(k)

G-2

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Collatek® Powder is a hydrocolloid wound dressing prepared from fibrous type I bovine collagen. Collagen protects the wound bed and newly formed granulation tissue by formation of a protective covering that is conducive to wound healing.

Collatek® Powder is designed to be a dry particulate product, this gives Collatek® Powder the advantage of being able to absorb many times its own weight in liquid exudate and the ability to conform to any wound site. For this reason, Collatek® Powder is designed for use on moderate to high exudating wounds with simple and complex wound irregularities.

Collatek® Powder is analogous in design as the commercially available predicate devices (hyCURE® Powder, Comfeel® Powder and Medifil® Particles).

#### 4. Materials

The material used for Collatek® Powder consists of fibrous Type I bovine collagen. Collagen is also the material use in manufacture of hyCure and Medifil Particles. Therefore, Collatek is similar to predicate devices in terms of materials used.

#### 5 Safety

Biocompatibility testing has confirmed that Collatek® Powder meets requirements as stated in FDA's Blue Book Memorandum G95-1 and ISO 10993. Results are given in Appendix K.

#### 6. Sterility and Packaging

Collatek® Powder will be packaged as a single use, disposable foil packet. The package and its contents will be sterilized using electron beam radiation. Collatek® Powder will be sterilized to a SAL index of  $10^{-6}$ . The sterility of Collatek® Powder will be ensured by validation in accordance with ANSI/AAMI/ISO 11137-1994.

#### Conclusion

Collatek® Powder is equivalent in design, function, materials and intended use and is therefore substantially equivalent to the commercially available predicate devices: hyCURE® Powder (Hymed Group Corporation), Comfeel® Powder (Coloplast Group, Ltd.) and Medifil® II Particles (BioCore Medical Technologies, Inc.). We therefore submit that Collatek® Powder is substantially equivalent to hyCURE® Powder, Comfeel® Powder and Medifil® II Particles.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 19 2007

Mr. Ajay Kumar  
Vice President of Operations  
BioCore medical Technologies, Inc.  
11800 Tech Road  
Suite #240  
Silver Spring, Maryland 20904

Re: K012990  
Trade Name: Collatek Powder  
Regulatory Class: Unclassified  
Product Code: KGN  
Received: September 6, 2001

Dear Mr. Kumar:

This letter corrects our substantially equivalent letter of October 24, 2001.

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 (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 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.

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Page 2 - Mr. Ajay Kumar

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 continue 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

09 000015

510(k) Number (if known): K012990

Device Name: Collatek Powder

Indications for Use:

Collatek Powder may be used in the management of:

- Partial and full thickness wounds
- Pressure (stage I-IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- 1st and 2<sup>nd</sup> degree burns
- Cuts, abrasions and surgical wounds

Contraindications:

Collatek powder should not be used on persons sensitive to bovine products.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription Use X  
(Per 21 CFR 801.109)

OR

510(k) Number K012990  
 Over-The-Counter-Use  
 (Optional Format 1-2-96)

BioCore Medical Technologies, Inc.  
Collatek Powder

Traditional 510(k)

D-1

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Figure 1: 0.5 g Product Label (1 unit)

<b>Collagen Powder</b>		<b>Store at room temperature, to a maximum of 25°C/77°F</b>
<b>Size: 0.5 g</b>	<b>Qty: 1 unit</b>	<b>Read instructions for use leaflet prior to use</b>
<b>Manufactured by:</b>	<b>Syntacoll</b>	<b>Precaution - Do not re sterilize. Discard all opened and unused devices. Device is sterile if the package is unopened and undamaged. Do not use if the package is damaged or seal is broken</b>
Syntacoll GmbH, Industriegebiet Saal, Donaustraße 24, 93342 Saal/Donau, Germany.		Lot -  Exp -
Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician		

Figure 1: 1.0 g Product Label (1 unit)

<b>Collagen Powder</b>		Store at room temperature, to a maximum of 25°C/77°F
Size: 1.0 g	Qty: 1 unit	Read instructions for use leaflet prior to use
Manufactured by:		Precaution - Do not re sterilize. Discard all opened and unused devices. Device is sterile if the package is unopened and undamaged. Do not use if the package is damaged or seal is broken
<b>Syntacoll</b>		Lot -
Syntacoll GmbH, Industriegebiet Saal, Donaustraße 24, 93342 Saal/Donau, Germany.		Exp -
Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician		

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Figure 1: 0.5 g Product Carton Label (10 units)

<b>Collagen Powder</b>		<b>Store at room temperature, to a maximum of 25°C/77°F</b>
<b>Unit size: 0.5 g</b>	<b>Qty: 10 units</b>	<b>Read instructions for use leaflet prior to use</b>
<b>Manufactured by:</b>		<b>Precaution - Do not re sterilize. Discard all opened and unused devices. Device is sterile if the package is unopened and undamaged. Do not use if the package is damaged or seal is broken</b>
<b>Syntacoll</b>		<b>Lot -</b>
Syntacoll GmbH, Industriegebiet Saal, Donaustraße 24, 93342 Saal/Donau, Germany.		<b>Exp -</b>
<b>Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician</b>		

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Figure 1: 1.0 g Product Carton Label (10 units)

<b>Collagen Powder</b>		<b>Store at room temperature, to a maximum of 25°C/77°F</b>
<b>Unit size: 1.0 g</b>	<b>Qty: 10 units</b>	<b>Read instructions for use leaflet prior to use</b>
<b>Manufactured by:</b>		<b>Precaution - Do not re sterilize. Discard all opened and unused devices. Device is sterile if the package is unopened and undamaged. Do not use if the package is damaged or seal is broken</b>
<b>Syntacoll</b>		<b>Lot -</b>
Syntacoll GmbH, Industriegebiet Saal, Donaustraße 24, 93342 Saal/Donau, Germany.		<b>Exp -</b>
Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician		

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### **Indications for Use**

Collagen Powder 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
- 1<sup>st</sup> and 2<sup>nd</sup> degree burns
- Dehisced surgical wounds
- Exuding wounds

### **Product Description**

Collagen Powder is an advanced wound care device comprising of Type I renatured bovine collagen. The collagen aids wound management. In the presence of wound exudate Collagen Powder transforms into a soft, gel-like particles conforming to the shape of the wound bed and thus maintains intimate contact with wound surface. The biodegradable collagen provides a scaffold for cellular invasion and capillary growth.

### **Precautions**

Collagen Powder should not be used when visible signs of infection are present in the wound area.

Discontinue the use of Collagen Powder and notify your doctor if excessive redness, pain, swelling or blistering occurs.

### **Contraindications**

Collagen Powder is not indicated for use on for third-degree burns. Collagen Powder should not be used on patients with known sensitivity or allergy to animal proteins.

### **Product Sizes**

0.5 g

1.0 g

### **Directions for Use**

Prepare wound bed per your standard wound care protocol and debride when necessary.

- Remove Collagen Powder vial from the pouch.
- Unscrew the cap and apply the Collagen Powder directly onto the wound bed.
- In order to maintain the correct position of Collagen Powder a secondary dressing is required to cover the Collagen Powder.
- After application, discard all packaging and any unused Collagen Powder.
- After initial application, reapply Collagen Powder to the wound as per physician recommendation.

### **Storage**

Collagen Powder should be stored away from direct sunlight. Store below 25°C/77°F.

The contents of each pack are considered sterile unless opened or damaged.

Do not use if individual pack damaged/opened.

Prior to use, check the use by date printed on the packaging.

Single use only.

Do not resterilize.

Keep out of sight and reach of children.

### **Distributed by**

## **Innocoll** Pharmaceuticals

Innocoll Pharmaceuticals,  
Midlands Innovation & Research Centre,  
Dublin Road, Athlone, Co. Westmeath, Ireland.

Manufactured on behalf of Innocoll Pharmaceuticals by Syntacoll GmbH Saal,  
Donaustraße 24, 93342 Saal/Donau Germany.





































































































































































































































































Food and Drug Administration  
Office of Device Evaluation &  
Office of In Vitro Diagnostics

**COVER SHEET MEMORANDUM**

**From:** Reviewer Name     *R. G. Gandy, M.D.*      
**Subject:** 510(k) Number     *K103648/S1*      
**To:** The Record

Please list CTS decision code     *SE*      
 Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))  
 Hold (Additional Information or Telephone Hold).  
 Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	<i>Attach IFU</i>	X	
510(k) Summary / <del>510(k) Statement</del>	<i>Attach Summary</i>	X	
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		NA
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )		X	
Is this a combination product? (Please specify category <u>    <i>N</i>    </u> , see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			NA
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			NA
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	X
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			X
Is clinical data necessary to support the review of this 510(k)?			X
For United States-based clinical studies <b>only</b> : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			NA
Does this device include an Animal Tissue Source?		X	
All Pediatric Patients age <= 21			X

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC.

X  
X  
X  
X  
X  
X  
X  
X  
X

Regulation Number

Class\*

Product Code

wound surgery, collapse      unclassified      KGN  
(\*If unclassified, see 510(k) Staff)

Additional Product Codes: \_\_\_\_\_

Review: [Signature] for David Krause      PR8B      9/14/2011  
(Branch Chief)      (Branch Code)      (Date)

Final Review: [Signature]      9/14/11  
(Division Director)      (Date)



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MEMORANDUM**

Food and Drug Administration  
Office of Device Evaluation  
9200 Corporate Boulevard  
Rockville, MD 20850

**Premarket Notification [510(k)] Review  
Traditional  
K103648/S1**

Date: 9/13/11  
To: The Record Office: ODE  
From: PL Hudson, Ph.D. Division: DSORD  
510(k) Holder: Innocoll Pharmaceuticals, Ltd.  
Device Name: Collagen Powder  
Contact: Mr. Aaron Wyse  
Phone: +353 (0) 90 66 66091  
Fax: +353 (0) 90 66 34895  
Email: [awyse@innocoll-pharma.com](mailto:awyse@innocoll-pharma.com)

*A. Wyse*  
*9/14/11*

**I. Purpose and Submission Summary**

The 510(k) holder would like to introduce Collagen Powder into interstate commerce. Additional information is necessary. The document had been placed on hold 2/25/11 and the sponsor was sent an email requesting the additional information necessary. The deficiencies and the sponsor's responses to those deficiencies are provided at the end of the review.

**II. Administrative Requirements**

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary	X		
Standards Form ( <b>Deficiency – reviewed at end of memo</b> )*	X		

\*The sponsor has cited conformance to a number of standards, however, they did not provide the required standards forms.

**Standards Met:** Collagen Powder has been assessed and meets the requirements of the following standards:

ISO 22442-1: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 1: APPLICATION OF RISK MANAGEMENT
ISO 22442-2: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 2: CONTROLS ON SOURCING, COLLECTION AND HANDLING
ISO 22442-3: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 3: VALIDATION OF THE ELIMINATION AND/OR INACTIVATION OF VIRUSES AND TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) AGENTS
ISO 10993-1:2009 BIOLOGICAL EVALUATION OF MEDICAL DEVICES – EVALUATION AND TESTING WITHIN A RISK MANAGEMENT PROCESS
ISO 11137 -1: 2006 STERILIZATION OF HEALTH CARE PRODUCTS - RADIATION - PART 1: REQUIREMENTS FOR DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES.

**III. Device Description**

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?			X
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?			X
Are “cleaning” instructions included for the end user?			X

The material is described as an off-white, collagen matrix that is produced from a highly purified collagen source. The Collagen Powder is stated as being produced from a native and re-natured, purified fibrillar Type I collagen. The collagen is obtained from cattle in New Zealand; New Zealand is considered to be free of BSE. The sponsor asserts that the Collagen Powder is manufactured **with** the same collagen used for the following, cleared collagen-based, medical devices: CollaGUARD (K061746), Collagen Sponge (K092805) and Collexa (K100574).

The Collagen Powder is manufactured by milling the freeze-dried, rendered collagen, and is then placed into vial containers (0.5 g and 1.0 g amounts) and gamma-irradiated for terminal sterilization. No information was provided regarding the particulate size of the material – or a comparison to the Collatek predicate particulate size (or other particulate, collagen powder, e.g., Medifil, Comfeel, etc., **Deficiency – reviewed at end of memo**).

(b)(4)

Test	Specification
(b)(4)	

Manufacturing process

(b)(4)



















Device Name: Collagen Powder

Indications For Use: Collagen Powder may be used for the management of wounds such as:

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

K092805 – Collagen Sponge

Device Name: Collagen Sponge

Indications For Use:

**Indications:**

Collagen Sponge may be used for the management of wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- First and second degree burns
- Partial and full thickness wounds
- Superficial injuries

K012990 – Collatek Powder

Indications for Use:

Collatek Powder may be used in the management of:

- Partial and full thickness wounds
- Pressure (stage I-IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- 1st and 2<sup>nd</sup> degree burns
- Cuts, abrasions and surgical wounds

The proposed indications for use are identified in the 2 predicate collagen-based wound dressings and have been identified in other collagen-based and non-collagen based wound dressings, and therefore are substantially equivalent.

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**V. Predicate Device Comparison**

The sponsor has chosen 2 collagen-based wound dressing predicates for comparison: K012990, Collatek Powder, and K092805, Collagen Sponge (the sponsor’s own predicate device. As noted above, the products are indicated for the same intended uses. Technologically, the devices consist of Type I collagen that is derived from either bovine Achilles’ tendons (subject device and sponsor’s predicate dressing, Collagen Sponge) or bovine hide which is another rich source of Type I collagen. The Collagen Sponge is provided in 70 and 280 mg sponge forms whereas the subject device and the Collatek Powder are both provided as milled, particulate collagen powders of 0.5 g (subject device only) and 1.0 g quantities.

**VI. Labeling**

The product label requires some revisions (**Deficiency – reviewed at end of memo**):

- The package label has a space for an expiration date – no information was provided to document an expiration date; the expiration date must be established on real time data or accelerated conditions data which has been validated by real time data.
- Within the Product Description of the product label, the device is referred to as “an advanced wound care device” – the term advanced is not defined and must be removed.

**VII. Sterilization/Shelf Life/Reuse**

The following sterilization information was provided:

Method:	Gamma irradiation
Dose:	25 kGy
Validation:	ISO 11137-1: Sterilization of health care products – radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
SAL:	10 <sup>-6</sup>
Endotoxin:	<0.25 EU/mL

**VIII. Biocompatibility**

The sponsor asserts that the collagen contained within the subject device is “made from the same bovine collagen as that used in Collagen Sponge (K092805 – also known as Collacare® (and previously Collatamp®) in EU markets) and CollaGUARD® (K061746). The only difference between the devices being the presentation i.e., powder, sponge and membrane, respectively.” The sponsor has provided the biocompatibility evaluations conducted on the CollagGUARD device (K061746).

<u>Test</u>	<u>Results</u>
Cytotoxicity	Pass
Irritation	Pass
Sensitization	Pass

The sponsor provided a rabbit pyrogenicity evaluation of the Collexa product (K100574). They found no temperature increase and therefore assert that the material is non-pyrogenic. The sponsor states that the collagen used to make either product is the same and therefore the results for the Collexa material can substitute for the subject device. The sponsor does have an endotoxin specification as well.

For devices being in contact with breached skin for periods of time >30 days, ISO 10993-1 recommends that medical devices be evaluated in: cytotoxicity, irritation, sensitization, sub-chronic toxicity (potentially implantation) and genotoxicity assessments. Previously, the sponsor had indicated, when this biocompatibility concern was raised, that the device was not intended for use beyond 30 days, i.e., it would be removed. In this case, the product consists of collagen particulates and can not be removed from the wound and therefore should be considered to be permanently implanted in the patient. The product requires evaluation as a long term implant (**Deficiency – reviewed at end of memo**). There is significant review experience with collagen-based wound dressings and therefore, the genotoxicity evaluation – based on traditional acid/base collagen extraction manufacturing processes – is not necessary. A sub-chronic toxicity evaluation or implantation assessment should be provided.

**IX. Software – N/A**

Version:		
Level of Concern:		
	<b>Yes</b>	<b>No</b>
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – N/A**

**XI. Performance Testing – Bench – none provided**

**XII. Performance Testing – Animal – none provided**

**XIII. Performance Testing – Clinical – none provided**

**XIV. Substantial Equivalence Discussion**

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?			If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See

[http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_4148/FLOWCHART%20DECISION%20TREE%20.DOC](http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough: Additional information was requested, and was provided regarding biocompatibility, standards forms, a detailed 510(k) Summary, labeling revisions (expiration date issue, terminology definition) and collagen particulate size identification with comparison to predicate materials.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

**XV. Deficiencies**

Additional information was requested from Mr. Wyse in the following email:

Hi Aaron,

In review of your application for the Collagen Powder product, FDA has identified the following issues which require additional information:

1. Standards forms required
2. Particulate size
3. Labeling
4. Implantation assessment
5. Revised 510(k) Summary

Deficiencies

1. Standards forms

You identified conformance to the following standards:

**Standards Met:** Collagen Powder has been assessed and meets the requirements of the following standards:

ISO 22442-1: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 1: APPLICATION OF RISK MANAGEMENT
ISO 22442-2: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 2: CONTROLS ON SOURCING, COLLECTION AND HANDLING
ISO 22442-3: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 3: VALIDATION OF THE ELIMINATION AND/OR INACTIVATION OF VIRUSES AND TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) AGENTS
ISO 10993-1:2009 BIOLOGICAL EVALUATION OF MEDICAL DEVICES - EVALUATION AND TESTING WITHIN A RISK MANAGEMENT PROCESS
ISO 11137 -1: 2006 STERILIZATION OF HEALTH CARE PRODUCTS - RADIATION - PART 1: REQUIREMENTS FOR DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES.

Effective January 2, 2008, all firms that choose to use a standard in the review of any new 510k (Traditional, Abbreviated or Special), need to fill out the new standards form (Form 3654) and submit it with their 510(k). the new standards form can be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>. Please provide a copy of this for as it pertains to this submission (e.g. any material, sterilization or mechanical testing standards).











# Innocoll Pharmaceuticals

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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:** September 13<sup>th</sup> 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) 87 0520845  
Fax: +353 (0) 9066 34895

**Proprietary Name:** Collagen Powder

**Common Name:** Topical Wound Dressing

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

### **Statement of Substantial Equivalence:**

Collagen Powder is substantially equivalent in materials of construction and intended use to Collagen Sponge (K092805) and Collatek Powder (K012990). Collagen Powder has been evaluated for its biocompatibility which meets requirements and is therefore substantially equivalent to the predicates delineated in this submission. Collagen Powder is manufactured from the same ingredients used for the manufacture of Collagen Sponge (K092805).

Collagen Powder 510k  
510k Summary

5 - 1

**Intended Use:**

Collagen Powder may be used for the management of wounds such as:

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

**Description:**

Collagen Powder is a collagen matrix in powder form intended for application as a wound management device. The product is supplied sterile for single use only.

**Biocompatibility and Testing:**

Evaluation of the biocompatibility of Collagen Powder was completed in line with the requirements of ISO 10993 -1: 2009. There are no new biocompatibility issues arising with the use of Collagen Powder; the materials of construction for Collagen Powder match Collagen Sponge (K092805).

Biochemical characterization of the collagen used to manufacture Collagen Powder was undertaken which characterized the collagen as being predominantly Type I collagen which is not denatured during the collagen rendering process.

Viral inactivation validation assessment was conducted on the collagen which demonstrates that the collagen material post processing can be assumed not to contain any pathogenic organisms.

Particle size analysis was conducted on the finished product which verified a particle size range for Collagen Powder.

**Conclusion:**

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

**Fife, Elizabeth \***

---

**From:** Microsoft Exchange  
**To:** 'awyse@innocoll-pharma.com'  
**Sent:** Wednesday, September 07, 2011 3:47 PM  
**Subject:** Relayed: K103648 Additional Information Received

**Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:**

'awyse@innocoll-pharma.com'

Subject: K103648 Additional Information Received

---

Sent by Microsoft Exchange Server 2007



COVER SHEET MEMORANDUM

From: Reviewer Name C. G. ... Ph.D.  
Subject: 510(k) Number K103648  
To: The Record

Please list CTS decision code AE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement:	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old), Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>)

Contact OC.

Regulation Number

Class\*

Product Code

(\*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:

*David Krone*  
(Branch Chief)

PRSB  
(Branch Code)

2/25/2011  
(Date)

Final Review:

*David Krone*  
(Division Director)

2/25/2011  
(Date)





**DEPARTMENT OF HEALTH AND HUMAN SERVICES      M E M O R A N D U M**

Food and Drug Administration  
Office of Device Evaluation  
9200 Corporate Boulevard  
Rockville, MD 20850

**Premarket Notification [510(k)] Review  
Traditional  
K103648**

Date: 2/25/11  
To: The Record      Office: ODE  
From: PL Hudson, Ph.D.      Division: DSORD  
510(k) Holder: Innocoll Pharmaceuticals, Ltd.  
Device Name: Collagen Powder  
Contact: Mr. Aaron Wyse  
Phone: +353 (0) 90 66 66091  
Fax: +353 (0) 90 66 34895  
Email: [awyse@Innocoll-pharma.com](mailto:awyse@Innocoll-pharma.com)

**I. Purpose and Submission Summary**

The 510(k) holder would like to introduce Collagen Powder into interstate commerce.  
**Additional information is necessary. The document has been placed on hold and the sponsor was sent an email requesting the additional information on 2/25/11.**

**II. Administrative Requirements**

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary	X		
Standards Form ( <b>Deficiency</b> )*		X	

\*The sponsor has cited conformance to a number of standards, however, they did not provide the required standards forms.























Device Name: Collagen Powder

Indications For Use: Collagen Powder may be used for the management of wounds such as:

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

K092805 – Collagen Sponge

Device Name: Collagen Sponge

Indications For Use:

**Indications:**

Collagen Sponge may be used for the management of wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- First and second degree burns
- Partial and full thickness wounds
- Superficial injuries

K012990 – Collatek Powder

Indications for Use:

Collatek Powder may be used in the management of:

- Partial and full thickness wounds
- Pressure (stage I-IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- 1st and 2<sup>nd</sup> degree burns
- Cuts, abrasions and surgical wounds

The proposed indications for use are identified in the 2 predicate collagen-based wound dressings and have been identified in other collagen-based and non-collagen based wound dressings, and therefore are substantially equivalent.

**V. Predicate Device Comparison**

The sponsor has chosen 2 collagen-based wound dressing predicates for comparison: K012990, Collatek Powder, and K092805, Collagen Sponge (the sponsor’s own predicate device. As noted above, the products are indicated for the same intended uses. Technologically, the devices consist of Type I collagen that is derived from either bovine Achilles’ tendons (subject device and sponsor’s predicate dressing, Collagen Sponge) or bovine hide which is another rich source of Type I collagen. The Collagen Sponge is provided in 70 and 280 mg sponge forms whereas the subject device and the Collatek Powder are both provided as milled, particulate collagen powders of 0.5 g (subject device only) and 1.0 g quantities.

**VI. Labeling**

The product label requires some revisions (**Deficiency**):

- The package label has a space for an expiration date – no information was provided to document an expiration date; the expiration date must be established on real time data or accelerated conditions data which has been validated by real time data.
- Within the Product Description of the product label, the device is referred to as “an advanced wound care device” – the term advanced is not defined and must be removed.

**VII. Sterilization/Shelf Life/Reuse**

The following sterilization information was provided:

Method:	Gamma irradiation
Dose:	25 kGy
Validation:	ISO 11137-1: Sterilization of health care products – radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
SAL:	10 <sup>-6</sup>
Endotoxin:	<0.25 EU/mL

**VIII. Biocompatibility**

The sponsor asserts that the collagen contained within the subject device is “made from the same bovine collagen as that used in Collagen Sponge (K092805 – also known as Collacare® (and previously Collatamp®) in EU markets) and CollaGUARD® (K061746). The only difference between the devices being the presentation i.e., powder, sponge and membrane, respectively.” The sponsor has provided the biocompatibility evaluations conducted on the CollagGUARD device (K061746).

<u>Test</u>	<u>Results</u>
Cytotoxicity	Pass
Irritation	Pass
Sensitization	Pass

The sponsor provided a rabbit pyrogenicity evaluation of the Collexa product (K100574). They found no temperature increase and therefore assert that the material is non-pyrogenic. The sponsor states that the collagen used to make either product is the same and therefore the results for the Collexa material can substitute for the subject device. The sponsor does have an endotoxin specification as well.

For devices being in contact with breached skin for periods of time >30 days, ISO 10993-1 recommends that medical devices be evaluated in: cytotoxicity, irritation, sensitization, sub-chronic toxicity (potentially implantation) and genotoxicity assessments. Previously, the sponsor had indicated, when this biocompatibility concern was raised, that the device was not intended for use beyond 30 days, i.e., it would be removed. In this case, the product consists of collagen particulates and can not be removed from the wound and therefore should be considered to be permanently implanted in the patient. The product requires evaluation as a long term implant (**Deficiency**). There is significant review experience with collagen-based wound dressings and therefore, the genotoxicity evaluation – based on traditional acid/base collagen extraction manufacturing processes – is not necessary. A sub-chronic toxicity evaluation or implantation assessment should be provided.

**IX. Software – N/A**

Version:		
Level of Concern:		
	<b>Yes</b>	<b>No</b>
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – N/A**

**XI. Performance Testing – Bench – none provided**

**XII. Performance Testing – Animal – none provided**

**XIII. Performance Testing – Clinical – none provided**

**XIV. Substantial Equivalence Discussion**

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	?	?	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?			If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See

[http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_4148/FLOWCHART%20DECISION%20TREE%20.DOC](http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough: The sponsor's product will be used as a permanent device – no biocompatibility evaluation of the product as recommended by ISO 10993-1, i.e., implantation or subchronic toxicity, was provided. Other administrative information, e.g., standards forms, detailed 510(k) Summary, labeling revisions (expiration date issue, terminology definition) and collagen particulate size identification and comparison to predicate materials is needed.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

**XV. Deficiencies**

Additional information was requested from Mr. Wyse in the following email:

Hi Aaron,

In review of your application for the Collagen Powder product, FDA has identified the following issues which require additional information:

1. Standards forms required
2. Particulate size
3. Labeling
4. Implantation assessment
5. Revised 510(k) Summary

1. Standards forms

You identified conformance to the following standards:

**Standards Met:** Collagen Powder has been assessed and meets the requirements of the following standards:

ISO 22442-1: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 1: APPLICATION OF RISK MANAGEMENT
ISO 22442-2: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 2: CONTROLS ON SOURCING, COLLECTION AND HANDLING
ISO 22442-3: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 3: VALIDATION OF THE ELIMINATION AND/OR INACTIVATION OF VIRUSES AND TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) AGENTS
ISO 10993-1:2009 BIOLOGICAL EVALUATION OF MEDICAL DEVICES – EVALUATION AND TESTING WITHIN A RISK MANAGEMENT PROCESS
ISO 11137 -1: 2006 STERILIZATION OF HEALTH CARE PRODUCTS - RADIATION - PART 1: REQUIREMENTS FOR DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES.

Effective January 2, 2008, all firms that choose to use a standard in the review of any new 510k (Traditional, Abbreviated or Special), need to fill out the new standards form (Form 3654) and submit it with their 510(k). the new standards form can be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>. Please provide a copy of this for as it pertains to this submission (e.g. any material, sterilization or mechanical testing standards).

## 2. Particulate size

You have specified that the collagen is milled and then, after processing, is packaged into 0.5 g and 1.0 g vial containers. Please provide the particulate size that is generated by the milling process and compare it to other collagen particulate wound dressing products for demonstration of substantial equivalence.

## 3. Labeling

The product label requires some revisions:

- The package label has a space for an expiration date – no information was provided to document an expiration date; the expiration date must be established on real time data or accelerated conditions data which has been validated by real time data. Expiration dating information should be provided or a statement that any expiration date placed on the product label will be based upon real time data or accelerated test data validated by real time data.
- Within the Product Description of the product label, the device is referred to as “an advanced wound care device” – the term advanced is not defined and must be removed.

## 4. Implantation assessment

The product - or material that constitutes the product - has been evaluated in cytotoxicity, irritation and sensitization biocompatibility studies. This product will be placed within wounds and will be absorbed. Removal of the particulates per dressing changes can not be 100% complete. FDA therefore believes the product should be evaluated as a material that will have permanent contact with tissue. Two assessments that are recommended for surface devices being placed on breached/compromised surfaces in addition to the standard 3 assessments already conducted, are genotoxicity and subchronic toxicity. Genotoxicity of this product is not considered necessary after review of the manufacturing process, i.e., reagents, etc., however FDA believes a subchronic or short term implantation evaluation is necessary. Please provide this information. If there is additional pre-clinical data which has been obtained for other products manufactured from the same collagen - and which include a particulate formulation - that information may adequately address this concern.

## 5. Revised 510(k) Summary

As already discussed, the 510(k) Summary should provide a brief description of all the information that was essential in demonstrating that the product was substantially equivalent to predicate wound dressings. Please revise the Summary accordingly.

The document is now placed on hold pending responses to these issues. If you have any questions, please contact me either via email or via phone (see below). Thanks.

Peter

Peter L. Hudson, Ph.D.  
Plastic and Reconstructive Surgery Branch  
Division of Surgical, Orthopedic and Restorative Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration  
301-796-6440

## XVI. Contact History

I sent an email to Mr. Wyse on 2/24/11. Additional information was requested via email on 2/25/11.

XVII. **Recommendation** – Additional information is necessary.

Regulation Number: No CFR listing/unclassified

Regulation Name: Wound dressing, collagen

Regulatory Class: Unclassified

Product Code: KGN

*P. J. ... Ph.D.*

Reviewer

*David Krone*

Branch Chief

*3/28/11*

Date

*2/25/2011*

Date

*I concur  
EAL*

**Hudson, Peter**

---

**From:** Hudson, Peter  
**Sent:** Friday, February 25, 2011 10:22 AM  
**To:** 'awyse@innocoll-pharma.com'  
**Cc:** Krause, David  
**Subject:** K103648 - on hold

**Attachments:** Picture (Enhanced Metafile)

Hi Aaron,

In review of your application for the Collagen Powder product, FDA has identified the following issues which require additional information:

1. Standards forms required
2. Particulate size
3. Labeling
4. Implantation assessment
5. Revised 510(k) Summary

1. Standards forms

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ISO 22442-2: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 2: CONTROLS ON SOURCING, COLLECTION AND HANDLING
ISO 22442-3: 2007 MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES - PART 3: VALIDATION OF THE ELIMINATION AND/OR INACTIVATION OF VIRUSES AND TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) AGENTS
ISO 10993-1:2009 BIOLOGICAL EVALUATION OF MEDICAL DEVICES – EVALUATION AND TESTING WITHIN A RISK MANAGEMENT PROCESS
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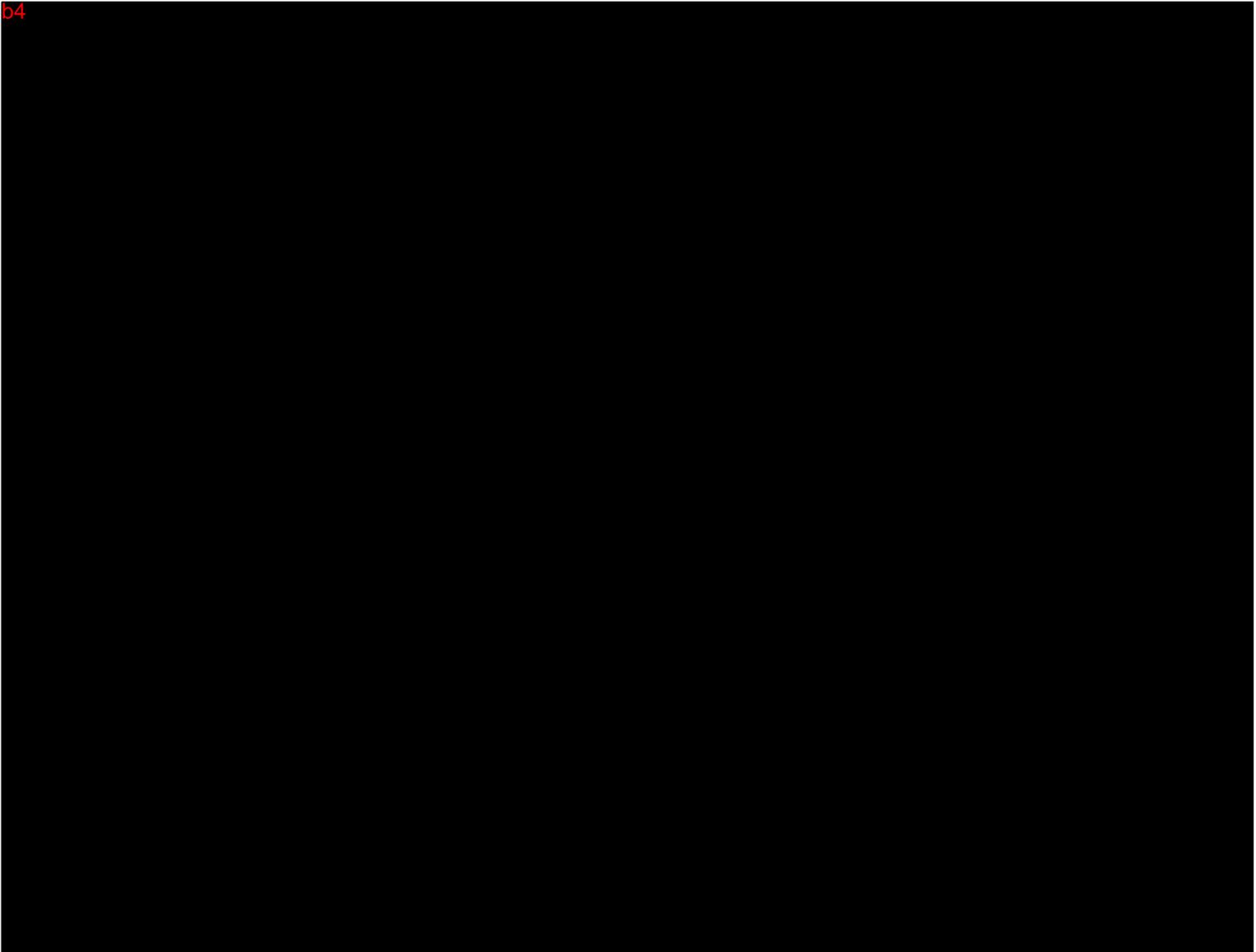
2. Particulate size

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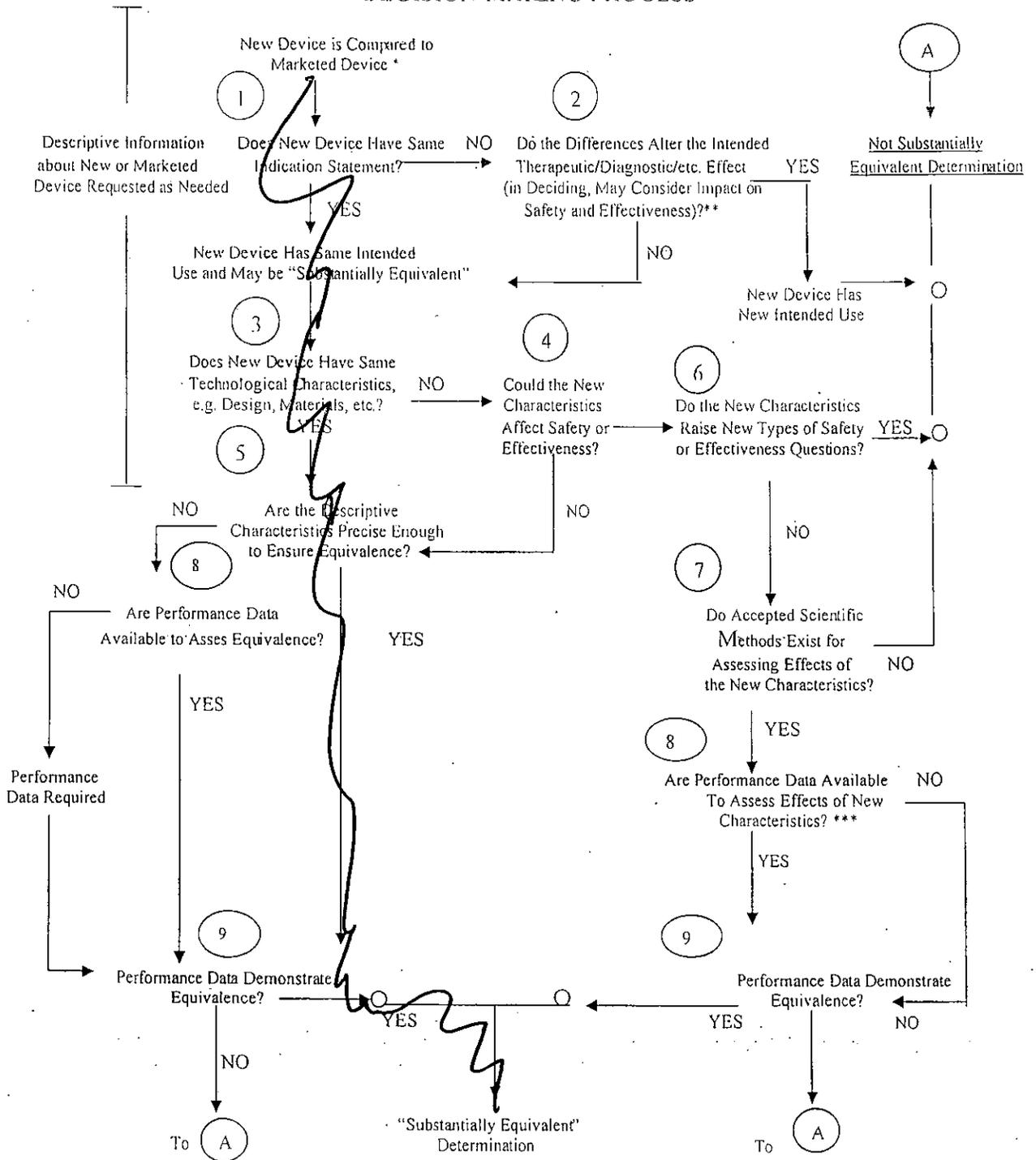
3. Labeling

The product label requires some revisions:

b4



### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



\* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

6

K103648/S1  
SU/D80KD

# Inn coll

Midlands Innovation & Research Centre  
Dublin Road, Athlone  
Co. Westmeath, Ireland  
Tel: +353 (0)90 6486834  
Fax: +353 (0)90 6486835

FDA CDRH DMC  
SEP 06 2011  
Received

SEP - 6 2011  
Received

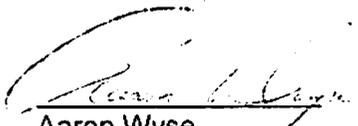
510(k) Number: K103648  
Product Name: Collagen Powder  
Date: 1<sup>st</sup> September 2011

K46

Dear Sir/Madam,

Please find enclosed the 510(k) premarket notification additional information as requested for Collagen Powder. Enclosed please find the additional information requested in duplicate hard copy and in electronic copy on the CD taped to the inner leaf of one of the files.

Kind Regards



Aaron Wyse  
Director of Regulatory Affairs  
Innocoll Pharmaceuticals Ltd.

Date: 1<sup>st</sup> September 2011

Department of Health and Human Services  
Food and Drug Administration

**STANDARDS DATA REPORT FOR 510(k)s**  
*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 22442-1:2007 Medical devices utilizing animal tissues and their derivatives - Part 1 Application of Risk Management

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes       No

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes       No

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....  Yes       No  
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes       No

Does this standard include acceptance criteria? .....  Yes       No  
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....  Yes       No  
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....  Yes       No  
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....  Yes       No

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....  Yes       No  
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....  Yes       No  
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....  Yes       No  
If yes, was the guidance document followed in preparation of this 510k? .....  Yes       No

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  
<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)  
<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>  
<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.  
<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>  
<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 22442-1:2007 Medical devices utilizing animal tissues and their derivatives - Part 1 Application of Risk Management		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER All	SECTION TITLE All	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION Risk Management is provided in Section 19 of this application, which includes assessment with ISO 22442-1		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 22442-2:2007 Medical devices utilizing animal tissues and their derivatives - Part 2 Controls sourcing, collection & handling

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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<b>EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE</b>		
STANDARD TITLE ISO 22442-2:2007 Medical devices utilizing animal tissues and their derivatives - Part 2 Controls sourcing, collection & handling		
<b>CONFORMANCE WITH STANDARD SECTIONS*</b>		
SECTION NUMBER All	SECTION TITLE All	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION Compliance with this standad is demonstrated through the quality management system. Statement of conformance is attached		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
<b>Paperwork Reduction Act Statement</b>		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

# Syntacoll

28<sup>th</sup> April, 2010**Subject: Bovine Collagen and Collagen Products**

To whom it may concern,

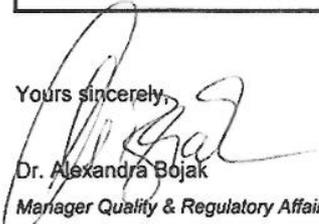
We hereby declare that bovine collagen and bovine collagen-based products manufactured by Syntacoll GmbH conforms to European Directive 93/42/EEC, to European Directive 2003/32/EC and the following harmonised standards in relation to medical devices:

- **EN ISO 22442-1:2007** Medical devices utilizing animal tissues and their derivatives - Part 1 Application of risk management (ISO 22442-1:2007)
- **EN ISO 22442-2:2007** Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2007)
- **EN ISO 22442-3:2007** Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (ISO 22442-3:2007)

Relevant information on the material of animal origin used are summarized in the table below:

	Bovine Collagen	Porcine Pepsin
Animal species of Origin	cattle	swine
Country of Origin	New Zealand	North America (USA)
Tissue	tendons	gastric mucosa
Veterinarian controls	Yes (MAF)	Yes (USDA)
Fit for Human Consumption	Yes	Yes
Supply / Supplier	customer-specific	commercial product (wholesaler)
Manufacturer	Syntacoll GmbH	Merck
Follow-up Product	bovine collagen (purified)	pepsin (purified)
Usage	starting material collagen products	excipient collagen rendering
Integral Part of the Medical Device	Yes	No
Quantitative elimination of material	n.a.	Yes
TSE/BSE relevant material	Yes	No
animal < 30 months	Yes	n.a.
non-invasive stunning technique	Yes	n.a.
closed herd	Yes	n.a.
Country of origin BSE-free	Yes	n.a.
Prion Inactivation / method validated	Yes	Yes
Virus Inactivation / method validated	Yes	Yes

Yours sincerely,


  
Dr. Alexandra Bojak

Manager Quality &amp; Regulatory Affairs

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Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes       No

FDA Recognition number <sup>3</sup> ..... # \_\_\_\_\_

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes       No

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....  Yes       No  
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes       No

Does this standard include acceptance criteria? .....  Yes       No  
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....  Yes       No  
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....  Yes       No  
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....  Yes       No

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....  Yes       No  
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....  Yes       No  
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....  Yes       No  
If yes, was the guidance document followed in preparation of this 510(k)? .....  Yes       No

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]  
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<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>  
<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.  
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER All	SECTION TITLE All	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION Compliance with this standad is demonstrated through the report for virus inactivation (Section 14 of this 510(k))		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>		

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-1:2009 Biological Evaluation of Medical Devices

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 2-156

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

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If no, include the results of testing in the 510(k).

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-1:2009 Biological Evaluation of Medical Devices		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER All relevant	SECTION TITLE All relevant	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Breach or compromised surface, prolonged contact		
DESCRIPTION Section 12: data demonstrate biocompatibility with requirements for breached or compromised surface for prolonged contact		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE <sup>1</sup>

ISO 11137-1:2006 Sterilization of Health Care Products - Radiation. Part 1 Sterilization for Medical Devices

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 14-276

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CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER All relevant	SECTION TITLE All	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * 25 kGy substantiation		
DESCRIPTION Protocol being drafted		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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## **Indications for Use**

Collagen Powder 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
- 1<sup>st</sup> and 2<sup>nd</sup> degree burns
- Dehisced surgical wounds
- Exuding wounds

## **Product Description**

Collagen Powder is a wound care device comprising of Type I renatured bovine collagen. The collagen aids wound management. In the presence of wound exudate Collagen Powder transforms into a soft, gel-like particles conforming to the shape of the wound bed and thus maintains intimate contact with wound surface. The biodegradable collagen provides a scaffold for cellular invasion and capillary growth.

## **Precautions**

Collagen Powder should not be used when visible signs of infection are present in the wound area.

Discontinue the use of Collagen Powder and notify your doctor if excessive redness, pain, swelling or blistering occurs.

## **Contraindications**

Collagen Powder is not indicated for use on for third-degree burns. Collagen Powder should not be used on patients with known sensitivity or allergy to animal proteins.

## **Product Sizes**

0.5 g

1.0 g

## **Directions for Use**

Prepare wound bed per your standard wound care protocol and debride when necessary.

- Remove Collagen Powder vial from the pouch.
- Unscrew the cap and apply the Collagen Powder directly onto the wound bed.
- In order to maintain the correct position of Collagen Powder a secondary dressing is required to cover the Collagen Powder.
- After application, discard all packaging and any unused Collagen Powder.
- After initial application, reapply Collagen Powder to the wound as per physician recommendation.

## **Storage**

Collagen Powder should be stored away from direct sunlight. Store below 25°C/77°F.

The contents of each pack are considered sterile unless opened or damaged.

Do not use if individual pack damaged/opened.

Prior to use, check the use by date printed on the packaging.

Single use only.

Do not resterilize.

Keep out of sight and reach of children.

## **Distributed by**

**Innocoll**  
Pharmaceuticals

Innocoll Pharmaceuticals,  
Midlands Innovation & Research Centre,  
Dublin Road, Athlone, Co. Westmeath, Ireland.

Manufactured on behalf of Innocoll Pharmaceuticals by Syntacoll GmbH Saal,  
Donaustraße 24, 93342 Saal/Donau Germany.

Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician  
Date of Issue: 01 September 2011











































# Innocoll Pharmaceuticals

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[www.innocoll-pharma.com](http://www.innocoll-pharma.com)

## **510(k) Summary**

**Date Prepared:** September 1<sup>st</sup> 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:** Collagen Powder

**Common Name:** Topical Wound Dressing

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

### **Statement of Substantial Equivalence:**

Collagen Powder is substantially equivalent in materials of construction and intended use to Collagen Sponge (K092805) and Collatek Powder (K012990). Collagen Powder has been evaluated for its biocompatibility which meets requirements and is therefore substantially equivalent to the predicates delineated in this submission. Collagen Powder is manufactured from the same ingredients used for the manufacture of Collagn Sponge (K092805).

Collagen Powder 510k  
510k Summary

5 - 1

**Intended Use:**

Collagen Powder 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

**Description:**

Collagen Powder is a collagen matrix in powder form intended for application as a wound management device. The product is supplied sterile for single use only.

**Biocompatibility:**

Evaluation of the biocompatibility of Collagen Powder was completed in line with the requirements of ISO 10993 -1: 2009. There are no new biocompatibility issues arising with the use of Collagen Powder; the materials of construction for Collagen Powder match Collagen Sponge (K092805).

**Conclusion:**

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