



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

MEDICAL CHEMICAL CORPORATION
KRIS KONTIS
VP REGULATORY AFFAIRS
19430 VAN NESS AVE
TORRANCE CA 90501-1104

May 28, 2015

Re: K150887
Trade/Device Name: Para-fix C&S Medium
Regulation Number: 21 CFR 866.2390
Regulation Name: Transport culture medium
Regulatory Class: I
Product Code: JSM, LIO
Dated: March 30, 2015
Received: April 3, 2015

Dear Dr. Kontis:

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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Sally A. Hojvat -S

Sally Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
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and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150887

Device Name

MCC Para-Fix C&S Medium

Indications for Use (Describe)

Para-Fix™ C&S Medium provides a method for collecting and preserving fecal specimens for the culture of intestinal enteric bacteria. Because the medium is capable of maintaining the bacteria for 96 hours, immediate transportation and processing of the specimen is not necessary.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Medical Chemical Corporation Para-Fix C&S Medium

Sponsor

Medical Chemical Corporation
19430 Van Ness Ave.
Torrance, California 90501-1104

Contact: Kris Kontis
Telephone number (800) 424-9394
Date: March 24, 2015

Device Name

Trade Names: MCC Para-Fix™ C&S Medium
Common Name: Transport Vials
Classification Name: Culture Media, Non-Propagating Transport (JSM)

Regulatory Information

Regulatory Section 21 CFR 866.2390
Classification Class I
Product Code: JSM, LIO
Panel Microbiology

Predicate Device

Meridian Para-Pak C&S
510(k) Number: K792712

Device Description

Para-Fix C&S Medium is a non-nutritive, buffered, isotonic solution with a pH indicator added. The medium also contains agar and sodium thioglycolate to maintain a low oxygen tension for the preservation of anaerobic species. The phenol red indicator will turn yellow when the solution is acidic and the conditions are not optimal for recovery of the intended organisms. Each 30 mL vial contains 15 ml of solution and a built in sample collection spoon. The kit is available with or without a multilingual instruction sheet and re-sealable bag.

Intended Use

Para-Fix C&S Medium provides a method for collecting and preserving fecal specimens for the culture of intestinal enteric bacteria. Because the medium is capable of maintaining the bacteria for 96 hours, immediate transportation and processing of the specimen is not necessary.

Indication(s) for Use

Para-Fix C&S Medium provides a method for collecting and preserving fecal specimens for the culture of intestinal enteric bacteria. Because the medium is capable of maintaining the bacteria for 96 hours, immediate transportation and processing of the specimen is not necessary.

Substantial Equivalence Statement

Medical Chemical Corporation Para-Fix C&S medium is similar in design, manufacturing and intended usage to the predicate device. Both the Para-Fix C&S and the predicate device are single use devices intended for collection and transport of clinical specimens containing enteric organisms.

Device Comparison Table

Technical Attribute	Para-Fix C&S (K150887)	Meridian Para-Pak C&S (K792712)
Container	30 mL Vial	30 mL Vial
Closure	Screw cap & spork	Screw cap & spork
Vial pressure test	95 kPa	unknown
Formulation	Cary Blair - modified	Cary Blair – modified
Fill volume	15 mL	15 mL
Storage temperature	20-30°C	20-30°C
Buffer system	Phosphate	Phosphate
Oxygen tension	Thioglycolate	Thioglycolate
pH indicator	Phenol red	Phenol red

Performance Testing

MCC Para-Fix C&S Medium is intended to be used as a non-propagating preservative for fecal specimens being able to prevent the significant loss of organisms that may be pathogenic and to prevent the overgrowth by normal intestinal flora. The bacteriostasis study demonstrates that Para-Fix C&S Medium preserves representative bacterial species for 96 hours at 2-8°C and 20-25°C. These species include potential pathogens that may be found in fecal samples: *Campylobacter jejuni*, *Clostridium difficile*, *Enterococcus faecalis*, *Bacillus subtilis*, *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Salmonella enterica*, *Shigella dysenteriae*, and *Vibrio parahaemolyticus*. The data showed that the number of viable organisms remained within $\pm 2 \log_{10}$ of the original inoculum. This is consistent with the intended use of the predicate device and demonstrates substantial equivalence.

Performance was tested in two ways. Para-Fix C&S Medium was tested for its ability to maintain enteric organisms using the plate count technique.

First C&S vials were seeded with suspensions of enteric organisms in the absence of fecal matrix. Vials were held at 2-8°C and 20-25°C and sampled at 0 and 96 hours by Swab Elution plate counts. Organisms were cultured on appropriate media to assure accurate recovery of seeded organisms. The performance criterion as specified by Clinical and Laboratory Standards Institute (CLSI), M40-A2 was met for the 10 enteric organisms previously listed. The results are shown in the following table:

All Enteric Organism recovery results for Para-Fix C&S Medium using Swab Elution Method.

Organism*	Hold Temperature	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 96 hrs	T=96 hrs Log reduction/ Log increase
<i>Escherichia coli</i>	2-8°C	1.6 X 10 ⁷	5.1 X 10 ⁷	0.51
	20-25°C	2.1 X 10 ⁷	2.5 X 10 ⁶	1.09
<i>Staphylococcus aureus</i>	2-8°C	1.6 X 10 ⁷	1.4 X 10 ⁷	-0.04
	20-25°C	1.5 X 10 ⁷	2.4 X 10 ⁷	0.20
<i>Pseudomonas aeruginosa</i>	2-8°C	8.1 X 10 ⁶	6.2 X 10 ⁶	-0.12
	20-25°C	9.2 X 10 ⁶	2.0 X 10 ⁶	1.34
<i>Salmonella enterica</i>	2-8°C	6.1 X 10 ⁷	5.8 X 10 ⁷	-0.02
	20-25°C	5.6 X 10 ⁷	2.1 X 10 ⁶	0.57
<i>Bacillus subtilis</i>	2-8°C	3.6 X 10 ⁶	4.0 X 10 ⁶	0.04
	20-25°C	4.6 X 10 ⁶	1.6 X 10 ⁷	0.54
<i>Vibrio parahaemolyticus</i>	2-8°C	9.8 X 10 ⁶	8.9 X 10 ⁶	-0.04
	20-25°C	9.8 X 10 ⁶	8.8 X 10 ⁶	-0.05
<i>Clostridium difficile</i>	2-8°C	1.2 X 10 ⁷	1.0 X 10 ⁷	-0.06
	20-25°C	1.1 X 10 ⁷	9.5 X 10 ⁶	-0.06
<i>Campylobacter jejuni</i>	2-8°C	5.8 X 10 ⁷	5.0 X 10 ⁷	-0.07
	20-25°C	4.0 X 10 ⁷	3.5 X 10 ⁷	-0.06
<i>Enterococcus faecalis</i>	2-8°C	2.3 X 10 ⁷	2.1 X 10 ⁷	-0.04
	20-25°C	2.2 X 10 ⁷	1.8 X 10 ⁷	-0.10
<i>Shigella dysenteriae</i>	2-8°C	2.2 X 10 ⁷	1.4 X 10 ⁷	-0.19
	20-25°C	2.4 X 10 ⁷	5.1 X 10 ⁶	-0.68

*0.5 McFarland microorganism suspension diluted with C&S Medium at 1:15

Second, Para-Fix C&S Medium was tested for its ability to maintain pathogenic enteric organisms spiked into clinically negative human fecal matrix. Clinically negative human fecal matrix was added to C&S vials that were then seeded with suspensions of enteric organisms. Vials were held at 2-8°C and 20-25°C and sampled at 0, 72, 96 and 120 hours by serial dilution plate counts, and by the Roll-Plate method using sterile swabs (Fisher 23-400-122). Organisms were cultured on selective media to assure accurate recovery of seeded organisms. The performance criterion as specified by CLSI M40-A2 was met for Swab Elution or the Roll-Plate method. The results are shown in the following tables:

Representative Enteric organism recovery results for Para-Fix™ C&S Medium using Roll-Plate Method.

Organism	Hold Temperature	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 72 hrs	Average CFU's Recovered: Time 96 hrs	Average CFU's Recovered: Time 120 hrs	T=120 hrs log reduction(-) or log increase (+)
<i>Salmonella enterica</i>	2-8°C	190	192	162	97	-0.29
	20-25°C	64	**	**	**	N/A
<i>Vibrio parahaemolyticus</i>	2-8°C	220	160	63	68	-0.51
	20-25°C	130	**	**	**	N/A
<i>Escherichia coli</i>	2-8°C	110	48	83	71	-0.19
	20-25°C	70	**	**	**	N/A
0.5 McFarland microorganism suspension diluted with fecal matrix and C&S Medium to 2.0×10^4 unless noted * diluted 2.0×10^5 ** Too numerous to count						

Representative Enteric organism recovery results for Para-Fix™ C&S Medium using Swab Elution Method.

Organism	Hold Temperature	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 72 hrs	Average CFU's Recovered: Time 96 hrs	Average CFU's Recovered: Time 120 hrs	T=120 hrs log reduction(-) or log increase (+)
<i>Salmonella enterica</i>	2-8°C	2.7×10^2	2.9×10^2	3.0×10^2	2.0×10^2	-0.13
	20-25°C	3.2×10^2	**	**	**	N/A
<i>Vibrio parahaemolyticus</i>	2-8°C	2.2×10^2	1.6×10^2	6.3×10^2	6.8×10^2	+0.49
	20-25°C	2.5×10^2	**	**	**	N/A
<i>Escherichia coli</i>	2-8°C	1.6×10^2	8.9×10^1	1.3×10^2	9.4×10^1	-0.23
	20-25°C	1.0×10^2	6.8×10^2	5.4×10^2	7.6×10^2	+0.88
*0.5 McFarland microorganism suspension diluted with fecal matrix and C&S Medium at 1:2000 ** Too numerous to count						

Based on the comparison of technological attributes, functional testing of preservation ability, we conclude that MCC Para-Fix C&S Medium is substantially equivalent to the predicate device - Meridian Para-Pak C&S.

Bioburden

MCC Para-Fix C&S Medium was tested for the presence/absence of bioburden which could interfere with subsequent procedures. At the time of manufacture bioburden was tested by an aerobic plate count. No viable organisms were found in any lots of product tested. A further test was performed after the end of expiration dating consisting of Gram staining each lot of product. No Gram-positive or Gram-negative organisms were detected by this method. We concluded that the process used to manufacture these media are effective at eliminating viable organisms and preventing the appearance of any organisms, viable or non-viable, that can be Gram stained.

Stability Testing

Para-Fix C&S vials were tested for the products to maintain bacteria inocula on both newly manufactured vials and vials exceeding the expiration dating of 18 months, representing a worst-case condition with respect to shelf-life stability. Performance was assessed by determining the bacterial counts at the time of inoculation and 96 hours later. In all cases the bacterial counts were within $\pm 2 \log_{10}$, as specified in the performance criteria for this study. We conclude that C&S Medium passes the performance criteria at the time of manufacture and after shelf-life expiration.

pH Stability

The pH value of the product at the time of testing was between 7.08 to 7.83 for Para-Fix C&S Medium.

Sterilization

MCC Para-Fix C&S vials are not sold as sterile. Although there is no sterility claim, the manufacturing process includes treatment of finished vials in a steam chamber for 30 minutes to eliminate bioburden.