510(k) Summary

Applicant

Medsep Corporation
A Subsidiary of Pall Corporation
1630 Industrial Park Street
Covina, CA 91722

Primary Contact

Edward J. Nelson
Medsep Corporation
Director, Regulatory and Scientific Affairs
1630 Industrial Park Street
Covina, CA 91722

Telephone Number: 626-915-8227
Fax Number: 626-915-8253

Date 510(k) Summary Prepared: August 21, 2002

Device Name

Device Name

Proprietary Name: Pall BDS

Common Name: Bacteria Detection System

Classification Name: System, detection, bacterial, for platelet transfusion products

Classification Code: MZC
Immunology (medical specialty)

Predicate Device

Traditional culture methodology and BacT/Alert Culture Bottles

Description of Device

The Pall BDS is a bacteria detection system which includes the Pall BDS Sample Set and the Pall BDS Oxygen Analyzer. The Pall BDS Sample Set is a sterile, stand-alone, disposable device to be sterilely docked to a leukocyte-reduced platelet storage bag for transfer of a test sample in a functionally closed system. The device includes tubing, a filter, a sampling site, and a culture bag containing a bacterial growth-enhancing agent and is used in conjunction with the Pall BDS Oxygen Analyzer component of the system. Proliferation of bacteria in the test sample results in consumption of oxygen, which can be used as a surrogate marker for bacterial growth. The system permits detection of bacterial growth in the test sample via the use of the Pall BDS Oxygen Analyzer to measure the oxygen content of the headspace gas in the Pall BDS Sample Set culture bag.

Intended Use

The Pall BDS Sample Set is intended to be used with the Pall BDS Oxygen Analyzer in qualitative procedures for the recovery and detection of aerobic and facultative anaerobic microorganisms (bacteria) for quality control testing of leukocyte-reduced apheresis or whole blood derived platelet units.

Comparison to Predicate Device

Comparisons were made to traditional culture methodology and to BacT/Alert Culture Bottles. The Pall BDS is similar to the predicate devices in intended use, and they are *in vitro* diagnostic test systems which are based on microbial growth. The BDS Sample Set is similar to BacT/Alert Culture Bottles in that both contain a microbial growth-enhancing reagent, both rely on changes in a respiration gas as a surrogate marker for bacterial growth, and both are used in conjunction with other instruments for qualitative detection of microbial growth via the surrogate markers. The BDS Sample Set is different from the predicate devices in that the latter contain culture media whereas the BDS Sample Set utilizes transferred plasma and the contained growth-enhancing reagent as the growth medium. The BDS Sample Set uses consumption of oxygen as the surrogate marker as measured by the Pall BDS Oxygen Analyzer component, whereas BacT/Alert Culture Bottles use the production of carbon dioxide in conjunction with the BacT/Alert Microbial Detection System.

Non-Clinical tests submitted

Testing was performed to establish the performance characteristics of the BDS Sample Set and comparisons to traditional culture methodology were included. Three sites transferred 2-3 mL of whole blood derived or apheresis platelet concentrates into the culture bag of the Pall BDS Sample Set following inoculation with approximately 100-500 CFU/mL of the following bacteria:

Staphylococcus aureus (ATCC # 27217), Klebsiella pneumoniae (clinical isolate), Serratia marcescens (ATCC # 43862), Staphylococcus epidermidis (ATCC # 49134), Streptococcus, beta (clinical isolate), Salmonella species (clinical isolate), Bacillus cereus (ATCC # 7064), Escherichia coli (ATCC # 25922), Enterobacter cloacae (ATCC # 29005), Pseudomonas aeruginosa (ATCC # 27853)

After sampling, the sets were incubated for 24 hours at 35°C and tested. Results of the studies from 3 test sites were as follows:

Bacteria	Site 1* number detected at 24 hours / number tested	Site 2* number detected at 24 hours / number tested	Site 3** number detected at 24 hours / number tested
Staphylococcus aureus	10/10	10/10	10/10
Klebsiella pneumoniae	10/10	9/10++	10/10
Serratia marcescens	10/10	10/10	10/10
Staphylococcus epidermidis	10/10	9/10+	8/10+
Streptococcus beta	9/10+	8/12+	10/10
Salmonella species	10/10	10/10	10/10
Bacillus cereus	10/10	10/10	10/10
Escherichia coli	10/10	10/10	10/10
Enterobacter cloacae	10/10	10/10	10/10
Pseudomonas aeruginosa	10/10	10/10	10/10

* Whole blood derived platelet units,
** Apheresis platelets units
\+ Remaining undetected units were tested and detected at 30 hours
++ Remaining undetected unit was not tested at 30 hours

Conclusion

The information and data contained herein demonstrate the Pall BDS performs as intended and is substantially equivalent to both traditional culture methodology, based on similarity of intended use and performance, and BacT/Alert Culture Bottles based on similarity of intended use and several technical characteristics.