510(K) SUMMARY

A. CONTACTS

MANUFACTURING SITE:

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INTRACEL Corporation
2005 NW Sammamish Road, Suite 107
Issaquah, Washington 98027

Phone: (425) 392-2992 ext. 638
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INTRACEL –ROCKVILLE

Cecilia Matos-Rosa
Regulatory Compliance
INTRACEL Corporation
1330 Piccard Drive
Rockville, MD 20850

Phone: (301) 258-5200 ext. 1124
Fax: (301) 977-3229

B. NAME OF DEVICE AND CLASSIFICATION

Bartels PRIMA System™ *Clostridium difficile* Toxin A Enzyme Immunoassay (EIA).

Trade/Proprietary Name:

PRIMA System – old
Bartels ELISA - new

Device Class:

Class I

510(k): K913229

C. LEGALLY MARKETED DEVICE

Bartels *Clostridium difficile* Toxin A EIA claims substantial equivalence to Bartels PRIMA System *Clostridium difficile* Toxin A EIA (K913229), currently in commercial distribution by INTRACEL, Corporation, Issaquah, WA (USA).

D. DEVICE DESCRIPTION:

The Bartels *Clostridium difficile* Toxin A EIA is a rapid method for the diagnosis of *Clostridium difficile* toxin A in human fecal samples, to be used as an aid in the detection of *Clostridium difficile*-associated disease. Microwell strips are coated with mouse IgG to *Clostridium difficile* toxin A, which selectively captures *Clostridium difficile* toxin A if present in a stool sample. Irrelevant specimen debris, including non-toxigenic strains of *Clostridium difficile*, is washed away. Rabbit immunoglobulins to *Clostridium difficile* toxin A and peroxidase-labeled goat anti-rabbit antibodies are added to the well concurrently in a coincubation step. During incubation, the rabbit anti- *Clostridium difficile* toxin A binds to captured toxin A. Peroxidase-labeled anti-rabbit antibodies bind to rabbit antitoxin, forming an antitoxin-conjugate complex. Unbound anti-toxin and conjugate are washed away. Solution 3 and Solution 4 are then added and color is produced if the antitoxin-conjugate complex, which possesses the enzyme for the substrate (HRP), is present. This color production is quantified spectrophotometrically and compared to negative and positive controls for determination of the presence of *Clostridium difficile* toxin A.

E. INTENDED USE STATEMENT

Bartels *Clostridium difficile* Toxin A Enzyme Immunoassay (EIA) is intended for the qualitative detection of *Clostridium difficile* Toxin A in human fecal specimens as an aid in the diagnosis of *Clostridium difficile* –associate diseases.

F. DESCRIPTION OF MODIFIED DEVICE COMPARED TO CLEARED DEVICE

INTRACEL has made no changes to the manufacturing process or quality control testing procedures for this product. The only changes relate to the incubation and washing conditions employed during performance of the immunoassay. The essential immunoreagents, underlying format and scientific principle remain the same with the improved product.

The following changes have been made for the kit assay procedure:

1. In the FDA cleared kit, the specimen is incubated in the antibody-coated well for 90 minutes at 37° C. In the improved format, the specimen is now incubated for only 30 minutes at 37° C.

2. In the FDA cleared kit, the product insert only specifies the use of an automated microwell washer after sample and conjugate incubation steps. In the improved format, the wash can also be conducted using a manual method. The manual wash procedure is being incorporated into the procedure in reaction to actual use conditions by the customers. The total number of washes remains at 4 for both procedures.

3. In the FDA cleared kit, the colorimetric substrate is incubated for 15 minutes at ambient temperature. In the improved assay procedure, the substrate is incubated for 30 minutes at 37°C.

To summarize, the total assay time is reduced from 135 minutes to 90 minutes. All incubation times are now performed at 37°C, and an alternative manual washing method was added.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 31 1999

Cecilia Matos-Rosa
Regulatory Compliance
INTRACEL Corporation
1330 Piccard Drive
Rockville, MD 20850

Re: K990664
Trade Name: Bartels PRIMA System *Clostridium difficile* Toxin A Enzyme Immunoassay (EIA)
Regulatory Class: I
Product Code: LLH
Dated: March 1, 1999
Received: March 1, 1999

Dear Ms. Matos-Rosa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K990664

Device Name: Bartels Clostridium difficile Toxin A EIA

Indications For Use:

Bartels *Clostridium difficille* Toxin A Enzyme Immunoassay (EIA) is intended for the qualitative detection of *Clostridium difficille* Toxin A in human fecal specimens as an aid in the diagnosis of *Clostridium difficille*-associated disease.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Wordy Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990664

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)