MAY 01 2002

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: K020576

Submitter:	ID Biomedical Corporation 1510 – 800 West Pender Vancouver, British Columbia Canada V6C 2V6 Telephone: (604) 431-9314 Fax: (604) 431-93789
Establishment Registration Number	3033040
Contact Person:	David N. Clary, Regulatory Affairs Associate ID Biomedical Corporation of Washington 19204 North Creek Parkway Suite 100 Bothell, WA 98011 Telephone: (425) 482-2601, Ext. 424 Fax: (425) 482-2502
Date Prepared:	February 20, 2002
Trade Name:	Velogene™ Genomic Identification Assay for VRE
Common Name:	Manual genomic identity test
Device Class	II
Classification Name:	Manual antimicrobial susceptibility test system
Special Controls	No special controls have been issued for *in vitro* diagnostic devices under sections 513 and 514.

INTENDED USE

The Velogene™ Genomic Identification Assay for VRE is a qualitative DNA probe test which utilizes Cycling Probe™ Technology (CPT) to detect the *vanA* and *vanB* genes in isolated colonies of presumptively identified enterococci.

DEVICE DESCRIPTION

The Velogene™ Genomic Identification Assay for VRE (Vancomycin Resistant Enterococci) is an *in vitro,* DNA probe based, diagnostic device that utilizes Cycling Probe™ Technology (CPT) to generate a spectrophotometric or visual result. Results can be generated 90 minutes after primary isolation.

The Velogene™ Genomic Identification Assay for VRE (hereafter may be referred to as the Velogene™ assay) utilizes a fluorescein labeled, biotinylated DNA-RNA-DNA chimeric probe providing an RNase H cleavable linkage when bound to the complementary sequence of the *vanA* or *vanB* gene. RNase H cleaves the RNA portion of the chimeric probe when it is hybridized to the target DNA. The uncleaved probe (*vanA* and *vanB* negative) is detected by binding of the fluoresceinated probe to a solid surface and attachment of an anti-fluorescein antibody conjugated with horseradish peroxidase, which converts a substrate to a colored end product. Cleavage of the probe (*vanA* or *vanB* positive) prevents binding of the probe-anti-fluorescein antibody enzyme complex, thus preventing formation of the colored end product. A vancomycin-resistant isolate (i.e. *vanA* or *vanB* gene is present) will produce a colorless result (or OD_{650} of ≤ 0.14). A vancomycin-sensitive isolate (i.e. *vanA* and *vanB* gene are absent) will produce a distinctly blue color (or OD_{650} of >0.14).

Each Velogene™ assay kit contains supplies sufficient to process 48 samples and consists of two separate reagent kits: a VRE Lysis/Cycle Kit and a VRE Microwell Detection Kit.

VRE Lysis/Cycle Kit

The Lysis/Cycle kit contains the reagents and components to:

- Lyse sample cells from an overnight culture of presumptively identified enterococci
- Clarify the test solution
- Complete the Cycling Probe™ Technology (CPT) process

VRE Microwell Detection Kit

The detection kit contains the reagents and components to:

- Stop the CPT process
- Bind the biotinylated end of both cleaved and uncleaved probes and remove the fluorescein labeled end of cleaved probes
- Complete the detection process

PREDICATE DEVICES

The predicate devices for ID Biomedical's Velogene™ Genomic Identification Assay for VRE kit are:

- Brain Heart Infusion (BHI) Agar with 6 µg/mL vancomycin, #K941444, Remel
- BHI Agar with 6 µg/mL vancomycin, #K964560, Hardy Diagnotics

Both are NCCLS approved tests for the detection of Vancomycin Resistant Enterococci (VRE).

SUMMARY OF SUBSTANTIAL EQUIVALENCE

Vancomycin Screen Agar

Vancomycin Screen Agar (BHI with 6 µg/mL Vancomycin) is a growth-based test that phenotypically identifies vancomycin resistance. Vancomycin screen agar is inoculated with a suspension of an overnight culture of enterococci and plates are examined for evidence of growth after a full 24 hours of incubation; growth indicates resistance to vancomycin.

Substantially equivalent characteristics:

- Both tests require isolates to be gram-positive, catalase-negative;
- Both tests identify vancomycin resistance in enterococci due to the *vanA* or *vanB* genes;
- Vancomycin screen agar and the Velogene™ assay identify vancomycin-resistant enterococci.

Substantially equivalent clinical performance:

A comparative study was performed at 3 geographically distributed U.S. sites using routinely submitted samples for microbiological identification. An agreement of 94.6% was obtained between the Velogene™ assay and the Vancomycin Screen Agar when 518 isolates of presumptively identified enterococci were tested (490/518).

ID Biomedical Corporation believes that the Velogene™ Genomic Identification Assay for VRE is substantially equivalent in characteristics and clinical performance to the currently marketed Vancomycin Screen Agar (BHI with 6 µg/mL Vancomycin) for the identification of vancomycin-resistant enterococci when applied in accordance with the intended use and proposed labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 01 2002

Mr. David N. Clary
Regulatory Affairs Associate
ID Biomedical Corporation
19204 North Creek Parkway, Suite 100
Bothell, Washington 98011

Re: k020576
Trade/Device Name: Velogene™ Genomic Identification Assay for VRE
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test System
Regulatory Class: Class II
Product Code: NIJ
Dated: February 20, 2002
Received: February 21, 2002

Dear Mr. Clary:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/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

INDICATIONS FOR USE

Applicant: ID Biomedical Corporation, Vancouver, British Columbia, V6C 2V6 Canada

510(k) Number: K020576 .

Device Name: Velogene™ Genomic Identification Assay for VRE

Indications For Use:

For the visual or spectrophotometric detection of the *vanA* and *vanB* genes in determining vancomycin resistance in enterococci isolated from culture.

Freddie M. Cook

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K020576

* For Prescription Use