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510(k) SUMMARY
(as required by 21 CFR 807.92)

The assigned 510(k) number is: K050709

Submitted by: Raija Koskivaara
Registration Manager
Wallac Oy
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Device Name: RESOLVE® Hemoglobin kit

Common Name: Isoelectric focusing of hemoglobins

Classification: Abnormal hemoglobin assay
Class II per 21 CFR § 862.7415

Product Code: GKA

Predicate Device: BioRad VARIANT Sickle Cell Short Program K924813
BioRad VARIANT nbs Sickle Cell Program K051072

Device Description:

The preparation and separation of hemoglobin is accomplished through the application of a hemoglobin sample onto a precast agarose gel containing RESOLVE Ampholytes pH 6–8. RESOLVE Ampholytes are composed of low molecular weight amphoteric molecules with varying isoelectric points. When an electrical current is applied to the gel, these molecules migrate through the gel to their isoelectric points (pI's) along the gel, forming a stable pH gradient.

The hemoglobin variants also migrate through the gel until they reach the area where their individual pI's equal the corresponding pH on the gel.

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At this point, the charges on the variants are zero and migration ceases. The electric field counteracts diffusion and the hemoglobin variant forms a discrete thin band.

Hemoglobin bands are visualized by using the JB-2 Staining System containing *o*-dianisidine. *o*-dianisidine, the active component of the Gel Stain Concentrate, is oxidized in the presence of hydrogen peroxide at the site of hemoglobin. This reaction produces an insoluble, colored precipitate proportional to the amount of hemoglobin.

Indications for Use:

The RESOLVE® Systems Hemoglobin kit is designed to separate whole blood, cord blood or dried blood spot specimen for detection of normal and variant hemoglobins by isoelectric focusing. The kit is designed to be run on a flat-bed electrofocusing unit. This assay is intended for use as an aid in the diagnosis of neonatal and adult hemoglobinopathies.

Comparison with Predicate Devices:

Features	Device RESOLVE® Hb kit	Predicate Device Bio-Rad VARIANT Sickle Cell Short Program (K924813)	Predicate Device Bio-Rad VARIANT nbs Sickle Cell Program (K051072)
	A. Similarities		
Intended Use	The RESOLVE® Systems Hemoglobin kit is designed to separate whole blood, cord blood or dried blood spot specimen for detection of normal and variant hemoglobins by isoelectric focusing. This assay is intended for use as an aid in the diagnosis of neonatal and adult hemoglobinopathies.	The VARIANT Sickle Cell Short Program is designed as a qualitative screen for the presence of hemoglobins F,A,S,D,C and E in eluates of neonatal blood collected on filter paper by high performance liquid chromatography (HPLC).	The VARIANT nbs Sickle Cell Program is designed as a qualitative screen for the presence of hemoglobins F,A,S,D,C and E in eluates of neonatal blood collected on filter paper by high performance liquid chromatography (HPLC).
Human Factors	For in vitro diagnostic use. For professional use only.	For in vitro diagnostic use. For professional use only.	For in vitro diagnostic use. For professional use only.

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Design- analytes identified	Hemoglobins F, A, E, D, S, C. In addition G and α- and β-thalassemia (e.g. Hb Bart's and HbH) can be identified.	Six retention time windows for hemoglobins F, A, E, D, S and C are shown.	Six retention time windows for hemoglobins F, A, E, D, S and C are shown.
Design- sample type	Neonatal dried blood spots on filter paper and in addition whole blood and cord blood specimen.	Neonatal dried blood spots on filter paper collection cards.	Neonatal dried blood spots on filter paper collection cards.
Design- target population	Neonates and also adults	Neonates	Neonates
Performance- precision	Total precision within laboratory: Hb A1C vs C: 2.82% Hb A vs F: 4.36%	Peak retention time precision is < 1% for all hemoglobin peaks.	Peak retention time precision is < 1% for all hemoglobin peaks.
	B. Differences		
Design- assay principle	Hemoglobins are separated based on their specific isoelectric point (pI) on the IsoElectric Focusing (IEF) gels.	Hemoglobins are separated in cation exhange HPLC column generating a pre-determined ionic strength gradient.	Hemoglobins are separated in cation exhange HPLC column generating a pre-determined ionic strength gradient.
Design- interpretation	Visual interpretation of hemoglobin bands compared to position marker (Iso Scan imaging system optional).	Pre-determined retention time windows for specific hemoglobin variants based on the retention time markers.	Pre-determined retention time windows for specific hemoglobin variants based on the retention time markers.

Summary of the performance data to establish Equivalence:

Method comparison

The method comparison of the RESOLVE® Hb kit to predicate device was performed at three sites. Two of these used the BioRad's HPLC method VARIANT Sickle Cell Short Program (1) as a comparative method and one site used the VARIANT nbs Sickle Cell Program (2). The studied samples were either routine DBS samples or retrospective samples. More than half of the samples were normal samples (FA). The rest of the samples had hemoglobin combinations with Hb S or hemoglobin combinations with other Hb variants such as Hb C, Hb D, Hb E, Hb G-Philadelphia, α-thalassemia and β-thalassemia.

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The results are presented in the following table:

	Number of specimens	HPLC method	Agreement -%	95% lower CL
Study 1	850	1	99.8	99.2
Study 2	837	2	97.7	96.7
Study 3	1031	1	99.1	98.4

Precision

The precision study was based on the results obtained from the comparison studies with the predicate devices. The variation was estimated by measuring the distance of certain Hb bands of FASC controls used in the studies. The analysis of variance approach was used to calculate the following variations:

	Number of specimens	Average distance (mm)	Within-gel precision (CV%)	Between-gel precision (CV%)	Total precision within laboratory (CV%)
Hb A_{1c} vs. Hb C	216	17.8	2.2	1.8	2.8
Hb A vs. Hb F	223	2.1	3.3	2.9	4.4

Substantial Equivalence:

The RESOLVE® Hb kit has the same Intended Use and Indications for Use as the Predicate Devices BioRad's HPLC method VARIANT Sickle Cell Short Program (K924813) and the VARIANT nbs Sickle Cell Program (K051072).

Based on the method comparison data and the precision results one may conclude that the RESOLVE® Hb kit is substantially equivalent to the cleared and currently marketed predicate devices BioRad's HPLC method VARIANT Sickle Cell Short Program and the VARIANT nbs Sickle Cell Program.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 8 2006

Mr. Raija Koskivaara
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P.O. Box 10, 20101 Turku
Finland

Re: k050709
Trade/Device Name: RESOLVE® Hemoglobin Kit
Regulation Number: 21 CFR § 864.7415
Regulation Name: Abnormal hemoglobin assay
Regulatory Class: II
Product Code: GKA
Dated: January 18, 2006
Received: January 20, 2006

Dear Mr. Koskivaara:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050709

Device Name: RESOLVE® Hemoglobin kit

Indications For Use: The RESOLVE® Systems Hemoglobin kit is designed to separate whole blood or cord blood samples for detection of normal and variant hemoglobins by isoelectronic focusing. The kit is designed to be run on a flat-bed electrofocusing unit.
This assay is intended for use as an aid in the diagnosis of neonatal and adult hemoglobinopathies.

Prescription Use ___✓___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (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 Clinical Laboratory Devices
510(k) Number K050709