11. 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: K003668 .

Date:	November 23, 2000
Submitter:	Wallac Oy Mustionkatu 6 20750 Turku, Finland
Telephone: Fax:	+358-2-2678111 +358-2-2678357
Contact person:	Gunnel Laaksonen Mgr RA
Trade Name:	AutoDELFIA™ Neonatal IRT kit (B005-112)
Common Name:	Fluoroimmunoassay for the determination of immunoreactive trypsin
Classification Name:	Chloride test system
Predicate Device:	DELFIA® Neonatal IRT kit (1244-034)

Device Description:

The AutoDELFIA Neonatal IRT assay is a solid phase, two-site fluoroimmunometric assay based on the direct sandwich technique in which two monoclonal antibodies (derived from mice) are directed against two separate antigenic determinants on the IRT molecule. Standards, controls and test specimens containing IRT are reacted simultaneously with immobilised monoclonal antibodies directed against a specific antigenic site on the IRT molecule and europium-labelled monoclonal antibodies (directed against a different antigenic site) in assay buffer. The assay buffer elutes IRT from the dried blood spots on the filter paper discs. The complete assay requires only one incubation step.

Enhancement Solution dissociates europium ions from the labelled antibody into solution where they form highly fluorescent chelates with components of the Enhancement Solution. The fluorescence in each well is then measured. The fluorescence of each sample is proportional to the concentration of IRT in the sample

510(k) Summary Cont'd

Intended Use:

The B005-112 AutoDELFIA Neonatal IRT kit is intended for the quantitative determination of immunoreactive trypsin (IRT) in blood specimens dried on filter paper as an aid in screening newborns for cystic fibrosis using the 1235 AutoDELFIA™ automatic immunoassay system.

Substantial equivalence:

The B005-112 AutoDELFIA Neonatal IRT kit was compared with our currently marketed 1244-034 DELFIA Neonatal IRT kit (K993697) and found to be substantially equivalent. The similarities and differences between the two kits are presented below:

Similarities:

- The intended use is the same. They are both intended for the quantitative measurement of IRT in blood specimens dried on filter paper used as an aid in screening newborns for cystic fibrosis.
- The assay principle is the same. They are both based on the time resolved fluoroimmunoassay principle.
- They both use the same antibodies.
- The analytical performance characteristics of the two kits are equivalent
- The expected values for the two kits are identical and the correlation between the two kits is good (Section 10, Method comparison with the predicative device).

Differences:

- The main difference between the two kits is the standard matrix. The 1244-034 version of the kit contains liquid standards. The standards in the B005-112 kit are dried blood spots on S&S 903 filter paper as are the neonatal screening samples.
- The highest standard in the 1244-034 kit is 1000 ng/mL blood, whereas the measuring range in the B005-112 is up to 500 ng/mL blood. The range has been cut down in the updated kit so that the screening cut-off level is more in the middle of the standard curve.
- Two levels of controls are included in the B005-112 kit, whereas the 1244-034 kit does not contain any controls.
- The B005-112 AutoDELFIA Neonatal IRT kit is intended for use with the automated 1235 AutoDELFIA immunoassay system (K935047), whereas the 1244-034 DELFIA Neonatal IRT kit is a manual method intended for use with time resolved fluorometers (K895240).

The similarities and differences are also shown in the following table:

	B005-112 AutoDELFIA Neonatal IRT kit	1244-034 DELFIA Neonatal IRT kit
Intended use	Same	Same
Antibodies / Cross reactivity	Same	Same
Standard range	0-500 ng/mL blood	0-1000 ng/mL blood
Standard matrix	Blood spots	Liquid
Controls	Blood spots (2 levels)	No controls
Tracer	Same	Same
Wash Concontrate	Same, provided separately	Same, included in the kit
Assay Buffer	Same	Same
Enhancement Solution	Same, provided separately	Same, included in the kit
Plates	Same, dry	Same, wet
Precision	CV% 3.9 – 10.0	CV% 6.3 – 12.0
Analytical sensitivity	Same	Same
Test handling	Automated	Manual

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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FEB 1 2 2001

Mr. Gunnel Laaksonen
Manager of Regulatory Affairs
PerkinElmer Life Sciences
Wallac Oy
Mustionkatu 6
20750 Turku, Finland

Re: K003668
Trade Name: AutoDELFIA™ Neonatal IRT kit (B005-112)
Regulatory Class: II
Product Code: CGZ
Regulatory Class: I reserved
Product Code JNO
Dated: January 22, 2001
Received: January 25, 2001

Dear Mr. Laaksonen:

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 Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 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

13. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003668

Device Name: AutoDELFIA™ Neonatal IRT kit (B005-112)

Indications For Use: This kit is intended for the quantitative determination of immunoreactive trypsin (IRT) in blood specimens dried on filter paper as an aid in screening newborns for cystic fibrosis.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003668

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)