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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: K993697

Date:	May 8, 2000
Submitter:	Wallac Oy Mustionkatu 6 20750 Turku, Finland
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Contact person:	Gunnel Laaksonen Mgr RA
Trade Name:	DELFIA® Neonatal IRT kit
Common Name:	Fluoroimmunoassay for the determination of immunoreactive trypsin
Classification Name:	Trypsin test system
Predicate Device:	Trypsik ^{125}I RIA kit (K 791202)

Device Description:

The DELFIA® Neonatal immunoreactive trypsin (IRT) assay is a solid phase, two-site fluoro-immunometric 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:

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.

Substantial equivalence:

The DELFIA® Neonatal IRT kit (Wallac Oy) was compared to the Trypsik ^{125}I RIA kit (Sorin Biomedica) currently distributed by DiaSorin in the US. Following similarities and differences were found:

Similarities:
- They are both intended for the measurement of immunoreactive trypsin (IRT).
- They are both based on the immunoassay principle.
- The performance of the kits is equivalent.
- The correlation between the two kits is good.

Differences:
- The intended use is the main difference between the two kits. The DELFIA® Neonatal IRT kit is used to measure IRT concentrations in blood spots as an aid in screening newborns for cystic fibrosis, while the Trypsik ^{125}I RIA kit is used to measure IRT concentrations in serum or plasma for the diagnosis of and treatment of pancreatic disease.
- The DELFIA® Neonatal IRT kit uses europium labelled tracer, which allows quantitation of IRT by fluorescence measurement, while the Trypsik ^{125}I RIA kit uses the ^{125}I labelled tracer and measures radioactivity.

The Similarities and differences are shown in the following table:

	DELFIA Neonatal IRT kit	**Trypsik ^{125}I RIA kit**
Intended use	Determination of IRT for screening newborns for cystic fibrosis	Determination of IRT for diagnosis of and treatment of pancreatic disease
Principle	Immunoassay	Immunoassay
Method	Time resolved fluorometry	Radioactivity
Sample	Dried blood spot	Serum and plasma
Standard range	0-1000 ng/mL blood	0 – 400 ng/mL serum
Precision	6.3 – 12 C.V. %	5.4 – 9.6 C.V. %
Detection limit	4 ng/mL blood	2.5 ng/mL serum

510(k) Summary Cont'd

The DELFIA® Neonatal IRT kit is substantially equivalent to the Trypsik ^{125}I RIA kit, when considering the principles and the technical performance of the two kits. The main difference between the kits is the intended use. The identification of the new specific use of the test is a result of the evolution of medical practice and we believe that there is today enough clinical evidence to show the usefulness of the determination of IRT as an aid in screening newborns for cystic fibrosis.

In addition the DELFIA Neonatal IRT kit (Wallac Oy) was compared with the sweat chloride test which is considered the standard for diagnosis of cystic fibrosis.

The sweat chloride test for the diagnosis of cystic fibrosis involves three steps:

Sweat stimulation (e.g. Wescor Sweat Inducer, K853973)
Sweat collection (e.g. Wescor Sweat collection system, K840472)
Quantitative sweat analysis for chloride, sodium, or both (e.g. Wescor Sweat Analyzer, K863395)

Localized sweating can be produced by the iontophoresis of the cholinergic drug pilocarpine nitrate into an area of skin. Iontophoresis uses an electric voltage so that an ionized drug carries current into the skin. The positively charged pilocarpine ions move away from the positive electrode and into the skin where they stimulate the sweat glands. After stimulation the sweat can be collected either by gause or filter paper or by microbore tubing. After the collection of an adequate amount of sweat it can be analyzed for chloride, sodium, or both. Chloride determinations provide greater discrimination and represents the most popular analyte in the United States.

Similarities and differences:

The DELFIA Neonatal IRT kit measures the concentration of immunoreactive trypsine in blood specimens while the sweat test measures the concentration of chloride in sweat.

Although the test principles are different they are both intended for the detection of cystic fibrosis. The DELFIA Neonatal IRT kit is used as a means of identifying a population of newborns who are at increased risk of having CF and the sweat chloride test is considered the standard for diagnosis of cystic fibrosis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 9 2000

Mr. Gunnel Laaksonen
Manager of Regulatory Affairs
PerkinElmer Life Sciences
Wallac Oy
P.O. Box 10
FIN-20101
Turku,
FINLAND

Re: K993697
Trade Name: DELFIA Neonatal IRT Kit
Regulatory Class: II
Product Code: CGZ
Dated: May 22, 2000
Received: May 24, 2000

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

12. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 993697

Device Name: DELFIA® Neonatal IRT kit

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.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993697

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)