JAN 3 0 2004

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ELECTROCHEMISTRY
SEPARATIONS
ANALYSIS

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:K032199.

Submitter:	ESA Inc. 22 Alpha Road Chelmsford, MA 01824 USA Phone: 978-250-7000 Fax: 978-250-7090
Contact Person:	Harold Asp Quality Assurance Manager
Date of Summary Preparation:	January 29, 2004
Device Name:	ESA Plasma Free Metanephrine Analysis Kit
Classification Name:	Catecholamine (total) Test System 862.1165
Predicate Device:	Model 5500 CEAS/Urinary Metanephrine and Norepinephrine
Statement of Intended Use:	The ESA Plasma Free Metanephrine Analysis Kit is intended for use in clinical laboratories that hold a CLIA certificate to perform tests of high complexity to measure endogenous free levels of the metanephrines (normetanephrine and metanephrine) in plasma using high performance liquid chromatography with electrochemical detection. The analysis of these analytes is used in the differential diagnosis of adult male and female patients with pheochromocytoma. For In Vitro Diagnostic Use Only

Description of Device:

The ESA Free Plasma Metanephrine Analysis Kit consists of reagents for the extraction of metanephrines (normetanephrine and metanephrine) sufficient for 100 plasma samples. Sample clean-up is achieved with ion exchange solid phase extraction. The final extracts are evaporated to dryness, reconstituted and analyzed via reversed phase ion-pair high performance liquid chromatography and electrochemical detection using the ESA CoulArray® detector. The multichannel electrode system oxidizes the metanephrines and the internal standard, 4-Hydroxy-3-methoxybenzlamine (HMBA), followed by reduction at a downstream electrode. Total chromatographic run time is approximately 28 minutes per sample. Quantitative data analysis and report generation is performed using ESA CoulArray for Windows Data Station.

Technical Characteristics Compared to Predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Quantitative Measurement of Plasma Free Metanephrines	Quantitative Measurement of Urinary Metanephrines
Indications for Use	Differential Diagnosis of Pheochromocytoma	Same
Methodology	High Performance Liquid Chromatography	Same
Differences		
Item	**Device**	**Predicate**
Matrix	Plasma	Urine

Conclusions:

Through the use of plasma samples, augmented plasma samples, standards and controls the performance and reliability of this assay has been verified. In so doing adequate sensitivity, precision, linearity, recovery, detection limits and immunity from interferences has been demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Harold Asp
Quality Assurance Manager
ESA, Inc.
22 Alpha Road
Chelmsford, MA 01824

Re: k032199
Trade/Device Name: ESA Plasma Free Metanephrine Analysis Kit
Regulation Number: 21 CFR 862.1165
Regulation Name: Catecholamines (total) test system
Regulatory Class: Class I
Product Code: CHQ
Dated: November 3, 2003
Received: November 4, 2003

Dear Mr. Asp:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032199

Device Name: ESA Plasma Free Metanephrine Analysis Kit

Indications For Use:

For In Vitro Diagnostic Use Only

The ESA Plasma Free Metanephrine Analysis Kit is intended for use in clinical laboratories that hold a CLIA certificate to perform tests of high complexity to measure endogenous free levels of the metanephrines (normetanephrine and metanephrine) in plasma using high performance liquid chromatography with electrochemical detection. The analysis of these analytes is used in the differential diagnosis of adult male and female patients with pheochromocytoma.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032199