OCT 4 - 2005

SECTION II

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: k052010

Submitter:
Cone Bioproducts
1008 N. River Street
Seguin, TX 78155

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Contact Person:
William K. Cone
Regulatory Affairs Officer
Telephone: (830)379-0197 ext. 203
Facsimile: (839)379-0471

Preparation Date:
September 1, 2005

Device Information:

Proprietary Name:	HbA1c Linearity Set
Regulation Number:	21 CFR§862.1660
Regulatory Name:	Quality Control Material (assayed and unassayed)
Product Code:	JJX
Regulatory Class:	Class I

Predicate Devices:
The HbA1c Linearity Set is substantially equivalent to LiniCAL Enzyme Calibration Verifiers (k040535) for its stated intended use.

Device Description:
The HbA1c Linearity Set is prepared from human blood to which stabilizers are added. The control is provided in liquid form for user convenience.

Intended Use:
Hemoglobin A1c Linearity is intended for use as quality control material to demonstrate linearity throughout the reportable range of Hemoglobin A1c (HbA1c%) for Immunoassay and HPLC test methods using protocols established in individual laboratories.

Comparison to Predicate Device(s):

Cone Bioproducts' HbA1c Linearity Set is substantially equivalent to LiniCAL Enzyme Calibration Verifiers (k040535) for its stated intended use.

Device Characteristics	Subject Device Hemoglobin A1c Linearity Set	Predicate Device(s) LiniCAL Enzyme Calibration Verifiers (k040535)
Intended Use	Hemoglobin A1c Linearity is intended for use as quality control material to demonstrate the linearity of Hemoglobin A1c (HbA1c%) for Immunoassay and HPLC test methods using protocols established in individual laboratories.	LiniCAL Enzyme Calibration Verifiers are intended for use in the clinical laboratory to verify calibaration and/or linearity of the Beckman Coulter Synchron Protein Systems. Five assayed levels of Alkaline Phosphatase, Alanine Aminotransferase, Amylase, Asparate Aminotransferase, Cholinesterase, Creatine Kinase, Creatine Kinase MB, Lactate Dehydrogenase, Lipase, Gamma Glutamyl Transferase, and Pancreatic Amylase are provided to allow monitoring of the reportable range.
Analyte	**Single Constituent** : A1c	**Multiple Constituents:** Alkaline Phosphatase, Alanine Aminotransferase, Amylase, Asparate Aminotransferase, Cholinesterase, Creatine Kinase, Creatine Kinase MB, Lactate Dehydrogenase, Lipase, Gamma Glutamyl Transferase, and Pancreatic Amylase
Methodology/ Analyzers	Compatible with Immunoassay and HPLC HbA1c test methods.	Beckman Coutler Sychron
Matrix	Human Blood	Human and Bovine Serum
Control Form	Liquid	Liquid
Levels	1-4 (4)	A-E (5)
Storage	-20°C	2°C to 8°C
Stability	Unopened vial stability (-20°C): 2 Years Opened vial stability (2-8°C): 14 days	Unopened vial stability (2-8°C): 3 Years Opened vial stability (2-8°C): 14 days

Summary:

The information provided in this pre-market notification demonstrates that Cone Bioproducts' A1c Linearity Set is substantially equivalent to LiniCAL Enzyme Calibration Verifiers (k040535). Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate device. The information supplied in this pre-market notification provides reasonable assurance that the Cone Bioproducts' A1c Linearity Set is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 4 - 2005

Mr. William Cone
Regulatory Affairs Officer
Cone Bioproducts
1008 N. River Street
Seguin, TX 78155

Re: k052010
Trade/Device Name: Cone Bioproducts HbA1c Linearity Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: September 1, 2005
Received: September 16, 2005

Dear Mr. Cone:

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,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

SECTION III

Indications for Use

510(k) Number (if known): k052010

Device Name: Cone Bioproducts' HbA1c Linearity Set

Indications For Use:

Hemoglobin A1c Linearity is intended for use as quality control material to demonstrate linearity throughout the reportable range of Hemoglobin A1c (HbA1c%) for Immunoassay and HPLC test methods using protocols established in individual laboratories.

Prescription Use ___X___ 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 In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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