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 K093548

807.92 (a)(1): Name: MEC Dynamics Corporation

Address: 90 Rose Orchard Way
San Jose, CA 95134
Phone: 408-428-9427
FAX: 408-456-0279
Contact: Mr. Emmanuel Mpock

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name: Avie™ A1C System

Common Name: Glycosylated hemoglobin assay

Classification: CFR §21.864.7470

807.92 (a)(3): Identification of the legally marketed predicate device

The Avie™ A1C Test System is substantially equivalent to other A1C test systems, and specifically, the Avie A1C System, cleared under premarket notification K091400 on 6/11/09.

807.92 (a)(4): Device Description

The Avie A1C Test is a point of care system that utilizes a Reader and disposable test cartridges to measure %A1C in whole blood samples. Whole blood from either capillary of venous is directly applied to the sample port of a test cartridge. Insertion of the test cartridge into the reader automatically prompts the operator to add diluent. Addition of diluent lyses the red bloods cell which allows both the A1C and total hemoglobin analytes to be measured. The test completes in less than three (3) minutes. Both the A1C and Total Hemoglobin (Total Hb) analytes are measured using its own distinct wavelength. Hemoglobin from the lyzed blood is converted to met-hemoglobin and is read at 420 nm. The concentration of hemoglobin is directly proportional to the intensity of met-hemoglobin concentration. For A1C the lysed blood is mixed with anti-hemoglobin antibodies conjugated to colored microparticles. After a predetermined time the microparticle mixture is automatically released onto a reagent strip where the

reacted and unreacted microparticle species are separated and read optically. The final displayed result is expressed as;

%A1C = (A1C ÷ Total Hb) ×100

MEC Dynamics, Corp. calibrates the Avie™ A1C System using National Glycohemoglobin Standardization Program (NGSP) certified laboratory value assigned blood samples. Lot specific information is transferred to the Avie™ A1C Reader via radio frequency identification (RFID).

807.92 (a)(5): Intended Use

The Avie™ A1C System test is a point of care system that quantitatively measures % A1C (glycated hemoglobin) in capillary and venous whole blood. The Avie™ A1C System consists of the Avie™ A1C System Reader, Avie™ A1C System Test Cartridge and Avie™ A1C System Diluent. The test is for physician directed prescription home use and professional use to monitor glycemic control in patients with diabetes mellitus. Single use, auto-disabling lancing devices are to be used in the professional setting. The device cannot be used in patients with hemoglobinopathies of Hemoglobin C and Hemoglobin D.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

Comparisons Between Avie A1C- modified and Avie A1C-cleared

Parameter	Avie™ A1C Test System Modified k093548	Avie™ A1C Test System K091400
Intended Use	SAME	Quantitative measurement of the percent of glycated hemoglobin
Indications for Use	Used in the management and treatment of diabetes, for monitoring long-term glycemic control. Device can not be used patients with elevated levels of HbC and HbD hemoglobinopathies.	Used in the management and treatment of diabetes, for monitoring long-term glycemic control.
Sample Type	SAME	Whole blood
Sample Preparation	Direct application, touch test cartridge to blood drop	Pipette 5µL into diluent vial, invert 5 times
Calibration	SAME	Cartridge calibration is automatic via RFID
Methodology	SAME	Immunoassay and general chemistry
Reagent Packaging	SAME	15 Cartridges in a desiccant lined, tamper evident canister
Testing Environment	SAME	Professional use and physician directed home use
Throughput	SAME	3 minutes/sample
Reagent Storage	Room Temperature 64-77°F (18-	Room Temperature 59-82°F (15-

	25° C)	28° C)
Display	SAME	% A1C
Diluent	15ml LDPE dropper multi-use bottle	1.0 ml single use Vial

807.92 (b)(1): Brief Description of Nonclinical Data

Studies were done that evaluated precision, linearity, interference, operational condition limits, NGSP traceability and venous vs. fingerstick whole blood matrices for the Avie™ A1C Test System. The *Avie™ A1C* Test System demonstrates precision within 5 %CV at each of two levels- normal and abnormal %A1C. The Avie™ A1C Test System is linear between 5 and 14 %A1C. The Avie A1C Test System is insensitive to high physiological levels of triglyceride and bilirubin, high therapeutic levels of various over-the-counter pharmaceuticals, and hemoglobin levels ranging from approximately 9 g/dL to 20 g/dL. The Avie™ A1C Test System may report unreliable results if there is high levels of, Hemoglobin D, Hemoglobin C or other hemoglobin variants. NGSP issued a certificate of traceability granting manufacturer certification to MEC Dynamics, Corporation.

807.92 (b)(2): Brief Description of Clinical Data

Clinical studies were conducted across four sites with approximately 350 comparative data. Subjects first performed one Avie™ A1C test on themselves, and this was followed by a second Avie™ A1C test performed by a health care professional at the site. Venous blood was collected and sent to the NGSP laboratory in Columbia, MO. The regression statistics from this testing are described below.

A comparison NGSP vs. Avie™ A1C capillary results by non-professional users testing 174 subjects showed regression statistics below:

Non-Professional Users (Capillary) = 0.976 (NGSP) + 0.151 r = 0.987

A comparison NGSP vs. Avie™ A1C capillary results by trained professional users testing 174 subjects showed regression statistics below:

Professional Users (Capillary) = 0.973 (NGSP) + 0.172 r = 0.988

A comparison between capillary Professional vs. capillary non-professional people gave a regression statistic below. Results were gathered from 169 capillary sample pairs run on the Avie system.

Non-Professional Users = 0.998(Professional Users) +0.019 r=0.984

A comparison of NGSP vs. Avie™ A1C venous results by trained professional users testing 279 whole blood samples is shown below:

Professional Users (Venous) = 0.972(NGSP) +0.210 r = 0.993

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Nonclinical and clinical testing was performed for the Avie™ A1C Test System. The test system was shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUL 20 2011

MEC Dynamics, Corp.
c/o Emmanuel Mpock
90 Rose Orchard Way
San Jose, CA 95134

Re: k093548
Trade/Device Name: Avie A1C System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP
Dated: July 1, 2011
Received: July 6, 2011

Dear: Mr. Mpock,

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
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): k093548

Device Name: Avie™ A1C System

Indications for Use:

The Avie™ A1C System test is a point of care system that quantitatively measures % A1C (glycated hemoglobin) in capillary and venous whole blood. The Avie™ A1C System consists of the Avie™ A1C System Reader, Avie™ A1C System Test Cartridge and Avie™ A1C System Diluent. The test is for physician directed prescription home use and professional use to monitor glycemic control in patients with diabetes mellitus. Single use, auto-disabling lancing devices are to be used in the professional setting. The device cannot be used in patients with hemoglobinopathies of Hemoglobin C and Hemoglobin D.

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

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

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093548