K072901

510(k) summary:

AMDL-ELISA DR-70® (FDP)

AMDL

According to the requirements of 21 CFR 807.92, the following information summarizes the safety and effectiveness if the test and is the basis for the determination of substantial equivalence.

The assigned 510(k) number is:

JUL - 1 2008

Submitter's Name and Address:

AMDL Inc.
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Contact: Gary Dreher

Date prepared: May 7, 2008

Device Names:

Proprietary Name:	AMDL-ELISA DR-70® (FDP)
Common/Usual Name:	Immunoassay for DR-70® (FDP)
Classification:	System, Test, Tumor Marker, Monitoring Regulation #: 866.6010 Intended Use: MONITORING AND MANAGEMENT OF COLORECTAL CANCER

Equivalency:

The AMDL DR-70 is substantially equivalent to TOSOH BioScience's AIA-PACK™ CEA (P910053).

Device Description:

For the quantitative analysis of DR-70® (FDP) in human serum for purposes of monitoring disease progression in patients previously diagnosed with colorectal cancer.

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510(k) summary:

AMDL-ELISA DR-70® (FDP)

AMDL

1.0 INTENDED USE

The DR-70® (FDP) ELISA is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of DR-70® (FDP) in human serum. Serial testing using the AMDL- ELISA DR-70® (FDP) is to be used as an aid in monitoring the disease progression in patients who have been diagnosed previously with colorectal cancer. Results of DR-70® (FDP) testing should be used in conjunction with other clinical modalities that are standard of care for monitoring disease progression in these patients.

2.0 SUBSTANTIAL EQUIVALENCE STATEMENT

AMDL Inc. is submitting this Pre-market Notification, 510(K), to convey its intention to manufacture for commercial distribution the AMDL-ELISA DR-70® (FDP). This assay is intended for the in vitro quantitative measurement of DR-70® (FDP) in human serum and is substantially equivalent to the TOSOH BioScience AIA-PACK™ CEA Assay (P910053) which was a PMA approved test prior to the down classification of the tumor markers used for colorectal cancer patients. The intended use of this product is as an aid in monitoring the disease status in patients who have been diagnosed previously with colorectal cancer.

AMDL-ELISA DR-70® (FDP) is substantially equivalent to the previously cleared TOSOH BioScience AIA-PACK™ CEA Assay (P910053) since both assays are equivalent in their intended uses, methodology, and their performance characteristics.

See Table 1 below for a comparison of the salient characteristics of the AMDL-ELISA DR-70® (FDP) to the currently marketed TOSOH BioScience AIA-PACK™ CEA (P910053).

TABLE 1 Comparison of Characteristics:
AMDL-ELISA DR-70® (FDP) vs. TOSOH BioScience AIA-PACK™ CEA (P910053)

	AMDL-ELISA DR-70® (FDP)	AIA-PACK™ CEA
Intended Use	Quantitative analysis of DR-70 (FDP) in human serum for purposes of monitoring disease progression in patients previously diagnosed with colorectal cancer	Quantitative analysis of CEA in human serum for purposes of monitoring status of patients previously diagnosed with colorectal cancer
Methodology	Immunoassay	Immunoassay
Assay Sample	Human serum	Human serum
Analyte	Fibrin/ogen Degradation Products	Carcinoembryonic Antigen
Antibody Types	Polyclonal (rabbit)	Monoclonal (mouse)
Assay Type	Sandwich Assay	Sandwich Assay
Reagent Form	Antibody-coated microwells	Antibody-coated mag beads
Sample Volume	10uL	100uL
Precision (Interassay)	≤ 4.7%	3.2-3.9%

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3.0 INTRODUCTION

This document describes a clinical trial using retrospective blood samples collected prospectively in which serum measurement of FDP using the AMDL, Inc. DR-70® (FDP) immunoassay was compared to the patients clinical disease status to aid in the monitoring of Subject tumor status, treatment outcome in Subjects previously diagnosed with colorectal cancer, and detection of disease recurrence. For AMDL, Inc.'s 510(k) submission of the DR-70® (FDP) immunoassay, CEA is the predicate device for the intended use and methodology only. The effectiveness of the DR-70® (FDP) immunoassay in the clinical trials will be evaluated based on a comparison to the clinical disease status. In this application, AMDL will demonstrate that the DR-70® (FDP) immunoassay is an informative test by addressing the null hypothesis that if the sum of the positive and negative concordance rates is less than one, then the test is not informative. Using the FDA guidelines, in which tumor markers used for the purposes of monitoring status in Subjects with a confirmed diagnosis of cancer are regulated via the 510(k) submission, performance of the DR-70® (FDP) immunoassay was compared to the clinical impressions of the treating physicians based on Subject interviews, physical examination, laboratory results, X-rays, CAT scans and MRI as they are used in routine clinical practice in managing colorectal cancer Subjects.

4.0 DEVICE DESCRIPTION

The AMDL, Inc. DR-70® (FDP) assay is an ELISA based assay utilizing removable strips in a 96 micro titer plate well format. The wells are coated with affinity purified rabbit anti-DR-70® (FDP) antibodies. The DR-70® (FDP) in diluted sera (1:200) is captured from the sera by these antibodies immobilized on the well of a micro titer plate. After a wash step, anti-DR-70® (FDP) antibodies conjugated to horseradish peroxidase are added to the wells. If the DR-70® (FDP) antigen is present, the anti-human fibrinogen peroxidase complex will bind to the captured tumor marker to form an immunological sandwich with the immobilized antibodies.

After a second wash step, the enzyme substrate 3,3',5,5'-tetramethylbenzidine (TMB) is added to the well. The end point is read in a micro plate reader at 450 nm once the reaction is stopped with 0.1N HCl. The intensity of the color formed is proportional to the amount of DR-70® (FDP) in the serum. The amount is quantified by interpolation from a standard curve using the calibrators provided with the kit.

5.0 PERFORMANCE TESTING

To determine the analytic validity of the DR-70® (FDP) immunoassay, the following performance tests were conducted.

5.1 Recovery

Serums from three normal subjects having DR-70® (FDP) values ranging from 0.3 µg/ml to 0.6 µg/ml and a control diluent buffer were spiked with a DR-70® (FDP) antibody solution to obtain expected levels ranging from 1.5 µg/ml to 10 µg/ml to

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represent the range of the DR-70® (FDP) calibrators. The values of DR-70® (FDP) in the spiked serum were measured and compared to the theoretical values and to values obtained for the control diluent buffer.

The experiment was designed to compare responses of the analyte in a biological sample versus the standard diluent to assess for any difference in assay response. Based on the overall analysis of results, the DR-70® (FDP) immunoassay kit is a quantitative test with concerns of sample matrix affects.

	DR-70 concentration value (µg/ml)					
Sample	No spike	Spike 1 1.5 µg/ml	Spike 2 2.5 µg/ml	Spike 3 5.0 µg/ml	Spike 4 7.0 µg/ml	Spike 5 10 µg/ml
Diluent buffer(5x)	0	1.517	2.649	4.586	6.983	10.94
Patient 1	0.428	1.743	2.908	4.839	7.057	13.11
Patient 2	0.576	1.520	2.680	4.848	7.050	11.95
Patient 3	0.464	1.598	2.967	5.193	6.701	10.88
Patient mean value	0.489	1.620	2.852	4.960	6.936	11.98
% Mean Recovery	-----	107%	108%	108%	99%	110%

5.2 Linearity

Serums from 5 colorectal cancer patients with DR-70® assay values in the range of 19.7 to 22.2 µg/ml were diluted with assay diluent buffer in a two-fold serial dilution series. For each CRC patient serum sample, a total of 9 DR-70® (FDP) dilution samples were tested. The table on the following page lists the % difference between the actual DR-70® (FDP) concentrations and the estimated DR-70® (FDP) concentrations (1st column) for each patient at each dilution. For each dilution, the average % difference is listed as well as the average % recovery. Grey boxes contain % differences per CRC patient at dilutions whose values were statistically non-linear. Values below the lowest calibrator included in the DR-70® (FDP) assay kit are in the non-linear portion of the DR-70® (FDP) assay curve.

% Difference Between Actual and Estimated DR-70® (FDP) Values in Linearity Study

Estimated DR-70® (FDP) Conc.	Dilution Ratio	% Difference per CRC Patient					Average % Difference	Average % Recovery
		1	2	3	4	5		
20	1	(14.5)	(0.1)	(6.9)	2.6	(3.2)	(4.4)	96
10	1/2	(2.3)	3.1	(7.4)	7.5	(5.7)	(1.0)	99
5	1/4	(2.6)	(1.4)	(0.3)	7.0	(2.1)	0.1	100
2.5	1/8	(21.2)	(5.8)	(3.2)	11.8	(16.8)	(7.0)	93
1.25	1/16	(11.0)	2.0	(8.6)	3.6	(14.5)	(5.7)	94
1.125	1/32	18.1	5.6	(0.1)	20.1	(5.8)	7.6	108
0.625	1/64	13.9	11.8	12.6	12.9	16.7	13.6	114
0.3125	1/128	23.6	23.6	24.4	36.5	21.2	25.9	126
0.15625	1/256	35.2	49.1	43.4	75.5	72.7	55.2	155

=indicates that these dilutions were statistically non-linear

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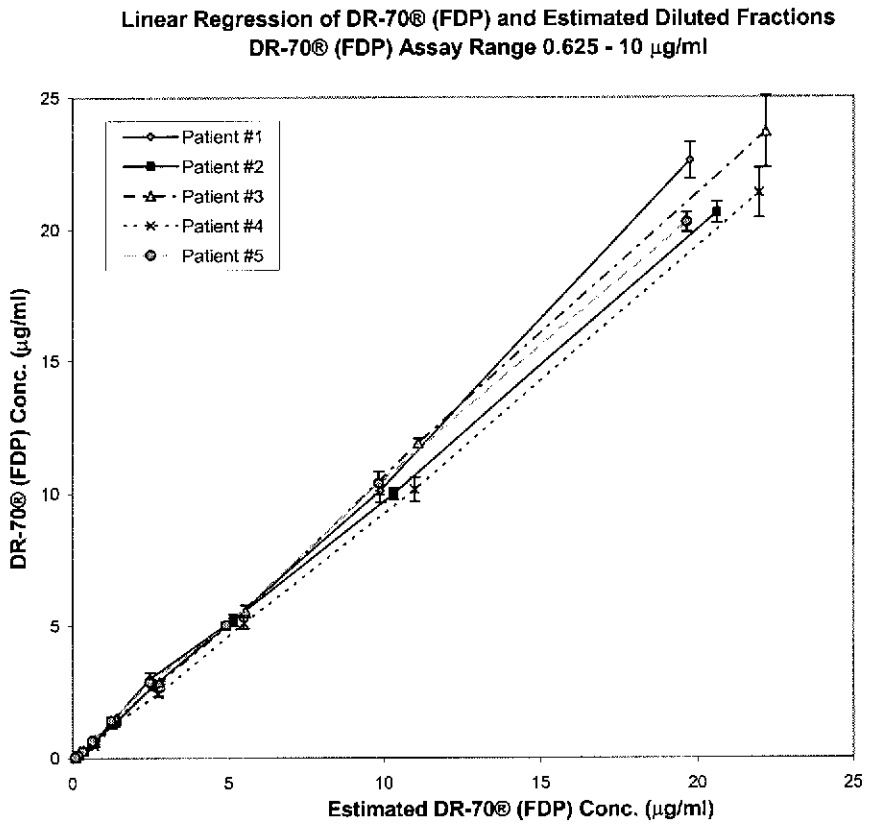
The results of the linearity study are presented in graphic form on the following page. For each of the 5 CRC patient serums, the estimated DR-70® (FDP) Conc. (µg/ml) is graphed against the actual DR-70® (FDP) Conc. (µg/ml) with the standard deviation among the 5 replicates at each point represented by the Y-axis error bars. For all of these patients, the DR-70® (FDP) concentrations were statistically found to be linearly related; except for those dilutions below a DR-70® (FDP) concentration of 0.625 µg/ml.



5.3 Precision

Imprecision was tested on the AMDL-ELISA DR-70® (FDP) using three serum pools and two quality control materials with concentrations of DR-70® (FDP) across the linear range of the assay run in quadruplicate in a randomized manner in two runs per day for twenty days at three sites using three manufactured lots. The results are as follows:

- The within run coefficient variation ranged from 1.27% to 5.53%.

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- Total variability ranged from a low of 9.91% at a concentration of 2.739 µg/ml to a high of 28.21% at 0.240 µg/ml.
- Day-to-day Variation across sample-site-lot combinations, the highest %CV measured was 8.58% with a nadir of 3.43%.
- The highest variation seen in run-to-run comparisons was 5.53%.

5.4 Analytical Sensitivity

The minimal detectable concentration (MDC) of DR-70® (FDP) is estimated to be 0.06 µg/ml. The MDC is defined as that concentration of DR-70® (FDP) corresponding to the absorbance that is two standard deviations from the mean rate of absorbance of 20 replicate determinations of a zero calibrator.

5.5 Functional Sensitivity

The functional sensitivity was determined by diluting the lowest non-zero calibrator serially, measuring the DR-70® (FDP) concentration and extrapolating to the point where the CV% = 20%. Functional sensitivity for the AMDL-ELISA DR-70® (FDP) is calculated as being between 0.052 and 0.063 µg/ml. This compares well to the Analytical Sensitivity of 0.06 µg/ml.

5.6 Interference

Interference is defined, for purposes of this study, to be recovery outside of 10% of the known specimen mean concentration.

- Added hemoglobin (up to 500 mg/dl) does not interfere with the assay.
- Added bilirubin (up to 30 mg/dl) do not interfere with the assay.
- Lipemia, as indicated by added triglyceride (up to 1000 mg/dl), does not interfere with the assay.
- Heparin (at concentrations of 500 U/ml) do not interfere with the assay.
- The following pharmaceutical agents were tested at levels indicated and found not to cause analyte recovery outside 10%: 5'-fluorouracil (Adrucil), 1.0 mg/ml; acetaminophen, 0.2 mg/ml; adriamycin (Doxorubicin HCl), 0.10 mg/dl; coumarin, 1.4 mg/ml; cyclophosphamide (Cytoxan), 0.25 mg/ml; Paclitaxel, 3.5 x 10^{-6};amethopterin hydrate (Methotrexate), 4.5 mg/ml; mitoxanntrone (Novatrone), 0.5 mg/ml; folinic acid (Leucovorin), 1.10 mg/ml, Mitomycin C, 0.06 mg/ml; cisplatin, 0.10 mg/ml.

5.7 Hook Effect

Studies were performed testing for hook effect in the AMDL-ELISA DR-70® (FDP). No evidence of a hook effect was found up to a concentration of 250 µg/ml.

6.0 CLINICAL STUDY

AMDL has conducted an extensive clinical testing on the DR-70 which demonstrates it's effectiveness in monitoring patients with colorectal cancer including:

- Normal Healthy Individuals

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- Benign diseases
- Malignant disease
- Serial monitoring with colorectal cancer

6.1 Distribution in percent of DR-70® (FDP) values within the Normal, Benign and Malignant disease cohorts

In each normal, benign and malignant disease cohort, the values for DR-70® (FDP) was analyzed for the different DR-70® (FDP) concentration levels within each disease cohort. The StatXact® software was utilized during this analysis to establish the exact 95% confidence intervals for the statistics. The distribution table is presented in the product labeling, and in Table 1 below.

TABLE 1. Distribution of percent of DR-70® (FDP) values

		Percent (%) 95% CI (lower-upper %)*			
Disease	# of subjects	0-1.4 µg/ml	1.5-2.4 µg/ml	2.5-4.9µg/ml	≥ 5.0 µg/ml
Normal	420	94.5 (91.9, 96.5)	5.0 (3.1, 7.5)	0.5 (0.1, 1.7)	0.0 (0.0, 0.9)
< 65 years	337	96.4 (93.9, 98.2)	3.3 (1.6, 5.8)	0.3 (0.0, 1.6)	0.0 (0.0, 1.1)
≥ 65 years	83	86.8 (77.5, 93.2)	12.1 (5.9, 21.0)	1.2 (0.0, 6.5)	0.0 (0.0, 4.4)
Benign	326	75.5 (70.4, 80.0)	6.8 (4.3, 10.0)	0.6 (0.1, 2.2)	17.2 (13.2, 21.7)
GU Disease	94	94.7 (88.0, 98.3)	4.3 (1.2, 10.5)	0.0 (0.0, 3.9)	1.1 (0.0, 5.8)
GI Disease	61	90.2 (79.8, 96.3)	3.3 (0.4, 11.4)	0.0 (0.0, 5.9)	6.6 (1.8, 16.0)
Pancreas	84	60.7 (49.5, 71.2)	15.5 (8.5, 25.0)	2.4 (0.3, 8.3)	21.4 (13.2, 31.7)
Heart Disease	87	58.6 (47.6, 69.1)	3.5 (0.7, 9.8)	0.0 (0.0, 4.2)	37.9 (27.7, 49.0)
Malignant	439	44.0 (39.3, 48.8)	24.2 (20.2, 28.4)	19.6 (16.0, 23.6)	12.3 (9.4, 15.7)
Colon	187	55.6 (48.2, 62.9)	21.4 (15.7, 28.0)	15.0 (10.2, 20.9)	8.0 (4.6, 12.9)
Lung	44	34.1 (20.5, 49.9)	38.6 (24.4, 54.5)	18.2 (8.2, 32.7)	9.1 (2.5, 21.7)
Liver	44	31.8 (18.6, 47.6)	27.3 (15.0, 42.8)	22.7 (11.5, 37.8)	18.2 (8.2, 32.7)
Breast	31	54.8	25.8	12.9	6.5

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		(36.0, 72.7)	(11.9, 44.6)	(3.6, 29.8)	(0.8, 21.4)
Ovarian	31	25.8 (11.9, 44.6)	6.5 (0.8, 21.4)	32.3 (16.7, 51.4)	35.5 (19.2, 54.6)
Cervical	28	50.0 (30.7, 69.4)	28.6 (13.2, 48.7)	7.1 (0.9, 23.5)	14.3 (4.0, 32.7)
Gall Bladder	19	42.1 (20.3, 66.5)	26.3 (9.2, 51.2)	31.6 (12.6, 56.6)	0.0 (0.0, 17.7)
Pancreas	28	25.0 (10.7, 44.9)	17.9 (6.1, 36.9)	35.7 (18.6, 55.9)	21.4 (8.3, 41.0)
Gastric/ Other	27	22.2 (8.6, 42.3)	33.3 (16.5, 54.0)	29.6 (13.8, 50.2)	14.8 (4.2, 33.7)

*Exact binomial confidence limits.

6.2 Statistical Analysis of DR-70® (FDP) Immunoassay as an Informative Test for Monitoring Disease Progression in Colon Cancer Patients.

The DR-70® (FDP) immunoassay was evaluated as an informative test for monitoring disease progression in colorectal cancer patients. An informative test must provide evidence to show that its performance is greater than the clinical diagnoses based on chance alone. There are many measures that can be used to quantify the value of cancer markers including the receiver operating characteristic (ROC) curve, sensitivity, specificity, predictive value positive, and predictive value negative. While the most useful measures for the clinician are the predictive values, these are rarely used because of their reliance on the prevalence of disease. Measures independent of the prevalence of disease such as ROC, sensitivity and specificity are most frequently studied. Furthermore, the predictive values are functions of sensitivity, specificity, and prevalence.

Serial samples were taken from 112 colon cancer patients resulting in 446 paired observations in which a DR-70 reading and a determination of disease progression were obtained. Since several patients had signs of progression even at the first examination, it was decided to attempt to determine the relationship between DR-70 and progression at successive visits. Thus from the data, a variable was derived by taking the ratio of a subsequent DR-70 reading and the previous reading. This measure is intended to determine the increase from a previous reading as a means of providing information on progression. A determination was made that a meaningful increase to determine evidence of progression was 15% increase or more. Thus, if the ratio was 1.15 or higher, the DR-70 test was deemed to be positive, otherwise it was deemed to be negative and this determination was paired with the finding at that visit of progression or not.

The resulting 335 paired observations from the post baseline sampling were evaluated in two ways. The initial analysis presents estimates directly from the data. This analysis is followed by a bootstrap sample for each patient by randomly sampling one

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visit at for each sample and recording the sensitivity or specificity for that visit. Note that if there was a progression and the sensitivity would be 1 if the DR-70 increased from the previous visit by 15% or more and 0 if it did not. If there were no progression at that visit, then there would be no sensitivity reported at that visit, but the specificity would be reported as a 1 if the DR-70 value was below a 15% increase for that visit and 0 otherwise. For the per visit analysis, there were 135 visits for sensitivity and 198 visits for specificity.

A second analysis was done on a per patient basis in which the number of progressions across all visits for a given patient were used to compute a patient level sensitivity by taking the number visits that DR-70 increase by at least 15% among the number of visits that there was a progression. Similarly, the number of visits at which DR-70 had a lower than 15% increase divided by the number of visits in which there was a non-progression allowed the computation of a per patient specificity. Recall that if a patient had all progressions there would be no specificity for that patient and if a patient had all non-progressions, there would be no sensitivity for that patient. This resulted in a sample of 112 patients with at least one sensitivity, specificity, or both. This resulted in 70 estimates of per patient sensitivity and 86 estimates of per patient specificity.

The computed per visit sensitivity from the 335 per visit evaluations was 100*88/135= 65.19 with standard deviation (SD) 2.58, the specificity was 100*134/199= 67.34 with SD= 2.94, the sum of sensitivity and specificity was 132.53 with SD = 3.91, the PPV was 100*88/153= 57.52 with SD = 1.63, and the NPV was 100*134/181= 74.03 with SD = 2.44.

For the per patient analysis, the computed per visit sensitivity from the 112 per patient evaluations was 100*45.68/69 = 66.21, the specificity was 100*58.63/86= 68.18, the sum of sensitivity and specificity was 134.39, the PPV was 100*51.83/97= 53.44, and the NPV was 100*71.67/103= 69.58. There is no method to obtain variance estimates from this process, so the confidence intervals are obtained from the bootstrap evaluations below.

These data and analyses demonstrate that the DR-70 test when taken as a 15% or greater change from the previous visit, yields informative data regarding colon cancer progression. The DR-70® (FDP) immunoassay results must be used in conjunction with standard of care procedures for monitoring colorectal cancer patients.

7.0 General Conclusions from the 510(k) submission

The data demonstrates that the proposed DR-70® (FDP) immunoassay has the same intended use as legally marketed predicate device, similar technological characteristics as a legally marketed predicate device, and that DR-70® (FDP) immunoassay does not raise new questions of safety or effectiveness. As such, the data provided in the submission support a finding of substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 1 2008

AMDL, Inc.
c/o Mr. Gary Dreher
President and CEO
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Re: k072901
Trade/Device Name: AMDL ELISA DR-70® (FDP)
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: NTY
Dated: May 12, 2008
Received: May 13, 2008

Dear Mr. Dreher:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); 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 Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072901 .

Device Name: AMDL-ELISA DR-70® (FDP) .

Indications For Use: "The AMDL-ELISA DR-70® (FDP) immunoassay is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of DR-70® (FDP) in human serum. Serial testing using the AMDL- ELISA DR-70® (FDP) is to be used as an aid in monitoring the disease progression in patients who have been diagnosed previously with colorectal cancer. Results of DR-70® (FDP) testing should be used in conjunction with other clinical modalities that are standard of care for monitoring disease progression in these patients."

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 Device Evaluation (ODE)

Maria M Chan

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K072901