K081150

510(k) SUMMARY OF INFORMATION RESPECTING SAFETY AND EFFECTIVENESS
Date of Summary Preparation: December 1, 2008

JUN 16 2009

1 Name and Address of Submitter

Company name and address	:	Turklab Tıbbi Malzemeler San. ve Tic. A.S. A.O.S.B. 10040 Sokak No: 20 35620 Cigli Izmir / Turkey www.turklab.com.tr
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2 Device Name

Proprietary Name	:	Rapidan Optima Early Pregnancy Test Toyo Pregnancy Test
Common Name	:	hCG Pregnancy Test
Classification Name	: :	Kit, test, pregnancy, hCG, over the counter Kit, test, pregnancy, hCG, professional and laboratory use
Product Code	:	LCX, JHI
Class	:	II
21CFR §	:	862.1155

3 Legally marketed Devices

One Step HCG Urine Pregnancy Test, K043443

4 Device description

The device is a qualitative assay based on immuno chromatography principle used to detect elevated levels of hCG over the cut-off value of the device, thus showing signs of pregnancy.

Principle of the test; introduced from one end of the membrane, urine mobilizes the anti-hCG antibody complex and moves toward the other end of the membrane passing through the immobilized anti-hCG antibody test region and through the antibody recognizing control region. In the presence of hCG, the test line appears on the membrane together with the control line which confirms the antibody complex arrival to the other end of the membrane.

The assay procedure is very simple and fast (introduce sample and wait 5 minutes). The device is designed as draw sample into the pipette, and dispense it onto the sample well of the cassette or dip into sample for strip type. Sampling end is color coded. The interpretation of the result is very easy (2 lines: pregnant, 1 line: not pregnant) even for the lay person.

5 Intended Use

Rapid immunological test device under the brands mentioned above are intended for non-professional, over the counter use and for professional and laboratory use to detect elevated levels of Human Chorionic Gonadotropin (hCG) in human urine to aid in the detection of pregnancy.

6 Comparison with Predicate Device

The Device is substantially equivalent to the "One Step HCG Urine Pregnancy Test, K043443"

Comparison charts with the above predicate device is below:

Similarities		
Item	**Turklab Device** Rapidan Optima Early Pregnancy Cassette Test	**Predicate** Wondfo Cassette Test
Intended Use	**Qualitative detection of hCG for detection of pregnancy**	**Same**
Test Principle	**Chromatographic immunoassay**	**Same**
Specimen	**Urine**	**Same**

Differences		
Item	**Turklab Device** Rapidan Optima Early Pregnancy Cassette Test	**Predicate** Wondfo Cassette Test
Cut-off point	**20 IU/L**	**25 IU/L**
Traceability	**4th IS WHO**	**3rd IS WHO**
Intended Use	**For OTC**	**For professional and OTC**

Similarities		
Item	**Turklab Device** Toyo Pregnancy Test / Cassette & Strip	**Predicate** Wondfo Test / Cassette & Strip
Intended Use	**Qualitative detection of hCG for detection of pregnancy**	**Same**
Test Principle	**Chromatographic immunoassay**	**Same**
Specimen	**Urine**	**Same**
Intended Use	**For professional and OTC**	**Same**
Cut-off point	**25 IU/L**	**25 IU/L**

Differences		
Item	**Turklab Device** Toyo Pregnancy Test / Cassette & Strip	**Predicate** Wondfo Test / Cassette & Strip
Traceability	**4th IS WHO**	**3rd IS WHO**

7 - 1 Performance Data

Rapidan Optima Early Pregnancy Test / 20 IU cut-off Cassette

a- Non-clinical Performance Data (807.92/b-1) and Conclusions from Non-Clinical Tests (807.92/b-3)

No cross-reactivity was observed in any variant when tested 100 times each with below units:

LH 500 IU/L LH
FSH 1000 IU/L FSH
TSH 1000 IU/L TSH

Interfering Substances (Recovery):

Tests were done in duplicates; with an addition of one of below listed chemicals to the sample in given values.

Test duplicates were repeated with samples containing (0; 10; 20; 25; 40; 50; 10,000; 50,000; 100,000 and 200,000 IU/L) hCG.

h Albumin	: 10 g/L	h Haptoglobin	: 10 g/L
h Myoglobin	: 10 g/L	Cow milk	: 100 mg/L
Ascorbic acid	: 2 g/L	Salicylic acid	: 1 g/L
Fruit acid	: 4 g/L	Alcohol	: 5 ml/L
Cellulose	: 5 g/L	Peroxides	: 100 g/L
Bovine serum	: 100 g/L	Caffeine	: 20 mg/dl
Glucose	: 2,000 mg/dl	Hemoglobin	: 1 mg/dl
Protein	: 2,000 mg/dl	Atropine	: 20 mg/dl
Gentisic Acid	: 20 mg/dl		

No variations between duplicates were observed.

For pH and specific gravity study; tests were done triplicates at the hCG levels of 0, 10, 20, 25, 50, 80, 100 IU/L.

PH	: 4 to 9
Specific gravity	: 1.003 to 1.040

Varying sample pH and specific gravity within the ranges above have no significant effect on the assay results. No variations between triplicates were observed.

Reproducibility:

10 different concentrations (0; 10; 20; 25; 40; 50; 10,000; 50,000; 100,000 and 200,000 IU/L) was prepared and test devices were tested 100 times with each concentration. Tests were done in duplicates. Total of 2,000 tests were done.

No result deviation is observed in any test.

b- Clinical Performance Data (807.92/b-2) and Conclusions from Non-Clinical Tests (807.92/b-3)

□ **Comparison Study for OTC use: The purpose of the study was to comparison of the Turklab' OTC devices (Rapidan Optima Cassette Test) with Predicate OTC devices (Wondfo Cassette Test) performing by lay users and professional.**

The results of this study are as below:

(Ref. Table A-1 at the attachment, S. 5.2.1.1 - 03. Comparison Data Sheet)

Comparison between lay user and professional user for Rapidan Optima Cassette Test (20 IU cut-off)

Turklab' Rapidan Optima Cassette Test (20 IU cut-off)		**Lay User**		**Total**
		Positive	Negative	
Professional User	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

Comparison between Turklab' Rapidan Optima Cassette Test (20 IU cut-off) and predicate test performed by professional user

Professional user		**Predicate OTC test**		**Total**
		Positive	Negative	
Turklab' Rapidan Optima Cassette Test (20 IU cut-off)	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

Comparison between Turklab' Rapidan Optima Cassette Test (20 IU cut-off) performed by lay user and predicate test performed by professional user

Professional user / **Lay user**		**Predicate OTC test**		**Total**
		Positive	Negative	
Turklab' Rapidan Optima Cassette Test (20 IU cut-off)	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

All lay users considered the test easy to perform and the labeling instructions clear and easy to follow. The results showed that women of various ages, racial backgrounds, and educational backgrounds should be able to properly use this tests.

7-2 Performance Data

Toyo Pregnancy Test / 25 IU cut-off Cassette & Strip

a- Non-clinical Performance Data (807.92/b-1) and Conclusions from Non-Clinical Tests (807.92/b-3)

No cross-reactivity was observed in any variant when tested 100 times each with below units:

LH	500 IU/L LH
FSH	1000 IU/L FSH
TSH	1000 IU/L TSH

Interfering Substances (Recovery):

Tests were done in duplicates; with an addition of one of below listed chemicals to the sample in given values.

Test duplicates were repeated with samples containing (0; 10; 20; 25; 40; 50; 10,000; 50,000; 100,000 and 200,000 IU/L) hCG.

h Albumin	: 10 g/L	h Haptoglobin	: 10 g/L
h Myoglobin	: 10 g/L	Cow milk	: 100 mg/L
Ascorbic acid	: 2 g/L	Salicylic acid	: 1 g/L
Fruit acid	: 4 g/L	Alcohol	: 5 ml/L
Cellulose	: 5 g/L	Peroxides	: 100 g/L
Bovine serum	: 100 g/L	Caffeine	: 20 mg/dl
Glucose	: 2,000 mg/dl	Hemoglobin	: 1 mg/dl
Protein	: 2,000 mg/dl	Atropine	: 20 mg/dl
Gentisic Acid	: 20 mg/dl		

No variations between duplicates were observed.

For pH and specific gravity study; tests were done triplicates for cassette and strip type tests at the hCG levels of 0, 10, 20, 25, 50, 80, 100 IU/L.

PH	: 4 to 9
Specific gravity	: 1.003 to 1.040

Varying sample pH and specific gravity within the ranges above have no significant effect on the assay results. No variations between triplicates were observed.

Reproducibility:

10 different concentrations (0; 10; 20; 25; 40; 50; 10,000; 50,000; 100,000 and 200,000 IU/L) was prepared and each test devices were tested 100 times with each concentration for cassette and strip type tests. Tests were done in duplicates. Total of 4,000 tests were done.

No result deviation is observed in any test.

b- Clinical Performance Data (807.92/b-2) and Conclusions from Non-Clinical Tests (807.92/b-3)

- **Comparison Study for OTC use: The purpose of the study was to comparison of the Turklab' OTC devices (Toyo Cassette & Strip Tests) with predicate OTC devices (Wondfo Cassette & Strip Tests) performing by lay users and professional.**

The results of this study are as below:

Toyo Cassette Test
(Ref. Table A-2 at the attachment, S. 5.2.1.1 - 03. Comparison Data Sheet)

Comparison between lay user and professional user for Toyo Cassette Test (25 IU cut-off)

Turklab' Toyo Cassette Test (25 IU cut-off)		**Lay User**		**Total**
		Positive	Negative	
Professional User	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

Comparison between Turklab' Toyo Cassette Test (25 IU cut-off) and predicate test performed by professional user

Professional user		**Predicate Cassette OTC test**		**Total**
		Positive	Negative	
Turklab' Toyo Cassette Test (25 IU cut-off)	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

Comparison between Turklab' Toyo Cassette Test (25 IU cut-off) performed by lay user and predicate test performed by professional user

Lay user \ Professional user		Predicate Cassette OTC test		Total
		Positive	Negative	
Turklab' Toyo Cassette Test (25 IU cut-off)	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

Toyo Strip Test

(Ref. Table A-3 at the attachment, S. 5.2.1.1 - 03. Comparison Data Sheet)

Comparison between lay user and professional user for Toyo Strip Test (25 IU cut-off)

Turklab' Toyo Strip Test (25 IU cut-off)		Lay User		Total
		Positive	Negative	
Professional User	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

Comparison between Turklab' Toyo Strip Test (25 IU cut-off) and predicate test performed by professional user

Professional user		Predicate Strip OTC test		Total
		Positive	Negative	
Turklab' Toyo Strip Test (25 IU cut-off)	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

Comparison between Turklab' Toyo Strip Test (25 IU cut-off) test performed by lay user and predicate test performed by professional user

Lay user \ Professional user		Predicate Strip OTC test		Total
		Positive	Negative	
Turklab' Toyo Strip Test (25 IU cut-off)	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

All lay users considered the test easy to perform and the labeling instructions clear and easy to follow. The results showed that women of various ages, racial backgrounds, and educational backgrounds should be able to properly use this tests.

- **Comparison Study for Hospital and Laboratory use: The purpose of the study was to comparison of the Turklab' hospital & laboratory use devices (Toyo Cassette & Strip Tests) with predicate hospital & laboratory use devices (Wondfo Cassette & Strip Tests) performing by professional.**

The results of this study are as below:

(Ref. Table B-1 at the attachment, S. 5.2.1.1 - 03. Comparison Data Sheet)

Comparison between Turklab' Toyo Cassette Professional Test (25 IU cut-off) and predicate professional test performed by professional user

Professional user		Predicate Professional Cassette Test		Total
		Positive	Negative	
Turklab' Toyo Cassette Professional Test (25 IU cut-off)	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

(Ref. Table B-2 at the attachment, S. 5.2.1.1 - 03. Comparison Data Sheet)

Comparison between Turklab' Toyo Strip Professional Test (25 IU cut-off) and predicate professional test performed by professional user

Professional user		**Predicate Professional Strip Test**		**Total**
		Positive	Negative	
Turklab' Toyo Strip Professional Test (25 IU cut-off)	Positive	50	0	50
	Negative	0	50	50
Total		50	50	100

Professional user considered the test easy to perform and the labeling instructions clear and easy to follow.

For Rapidan Optima and Toyo Pregnancy Tests;

c- Other information (807.92/d):

Calibration: The devices are calibrated against the positive controls for hCG. (4th IS WHO)

Quality Control: Turklab' pregnancy tests have built in Quality Control Features. After addition of the urine sample, these colored bands migrate along the membrane at the leading edge of the dye conjugate and are "removed" from the test strip completely. When the test is complete, the end user will see a red colored band in the "C" area of the test strip on negative samples and a red colored band in the "T" and "C" area on positive samples. The appearance of the control "C" band indicates that the test strip is performing properly and serves as a procedural internal control. If there are no colored bands in the "C" area and "T" area or if there is no color band in "C" area even there is a band in the "T" area; this means "invalid" test result. It is informed to user as in instruction manuals of the test devices.

8 **Conclusion:** In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, Turklab Tıbbi Malzemeler San. ve Tic. A.Ş. concludes that the new devices are safe, effective and substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Turklab Medical Devices Inc.
c/o Ms. Hilda Cil
Deputy General Manager
10040 SK. Ataturk Organize
Sanayi Bolgesi Cigli
Izmir
Turkey 35100

JUN 16 2009

Re: k081150
Trade/Device Names: Rapidan Optima Early One Step hCG Urine Pregnancy Test
Toyo One Step hCG Urine Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI, LCX
Dated: May 29, 2009
Received: June 03, 2009

Dear Ms. Cil:

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); 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 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. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number: k081150

Device Name: Rapidan Optima Early One Step hCG Urine Pregnancy Test

Indication For Use:

Rapidan Optima Early One Step hCG Urine Pregnancy Test is an *in-vitro* diagnostic test for qualitative determination of human chorionic gonadotrophin (hCG) in human urine. It is intended for over the counter use to detect elevated (over the cut-off value of 20 IU/L) levels of human chorionic gonadotrophin (hCG) in human urine to aid in the detection of pregnancy.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _X___ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

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

510(k) K081150

Indication for Use

510(k) Number: k081150

Device Name: Toyo One Step hCG Urine Pregnancy Test

Indication For Use:

Toyo One Step hCG Urine Pregnancy Test is an *in-vitro* diagnostic test for qualitative determination of human chorionic gonadotrophin (hCG) in human urine. It is intended for over the counter use and for professional / laboratory use to detect elevated (over the cut-off value of 25 IU/L) levels of human chorionic gonadotrophin (hCG) in human urine to aid in the detection of pregnancy. Toyo Pregnancy Test has two formats, a cassette and a test strip format.

Prescription Use __X____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use _X___ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

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

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