K083184

TearLab™

MAY 14 2009

Section VI
510(k) Summary
Intended Use & Indications for Use

OcuSense, Inc., TearLab Osmolarity System

OcuSense, Inc.
12707 High Bluff Drive, Suite 200
San Diego, CA 92130

Phone: (858) 794-1422
Facsimile: (858) 794-1493
Contact Person: Michael Berg, VP Clinical & Regulatory Operations
Date Prepared: May 5, 2009

Name of Device:
TearLab™ Osmolarity System

Name/Address of Sponsor:
OcuSense, Inc., 12707 High Bluff Drive, Suite 200, San Diego, CA 92130

Common or Usual Name:
Osmometer

Classification Name:
Osmometer for Clinical Use

Predicate Devices:

1) Wescor, Inc., 5520 Vapro® Vapor Pressure Osmometer (Class I, Exempt)
2) Alcon Laboratories, Inc., Schirmer Tear Test (Class I, Exempt)
3) Touch Scientific, Inc., Touch Tear IgE Microassay Kit (Class II, K991316)
4) Dia-Screen Corp., Diascreen Reagent Strips (Class I, Non-exempt, K971976)

Intended Use & Indications for Use:
The TearLab Osmolarity System is intended to measure the osmolarity of human tears to aid in the diagnosis of patients with signs or symptoms of dry eye disease, in conjunction with other methods of clinical evaluation.

Section VI
510(k) Summary
Technological Characteristics

Device Description

The TearLab Osmolarity System is intended to measure the osmolarity of human tears to aid in the diagnosis of patients with signs or symptoms of dry eye disease, in conjunction with other methods of clinical evaluation. The device consists of the following components and accessories: One TearLab Reader, Two TearLab Pens, Two TearLab Electronic Check Cards, Single Use TearLab Osmolarity Test Cards, and TearLab Control Solutions.

The TearLab Osmolarity Test Card, in conjunction with the TearLab Osmolarity System, provides a quick and simple method for determining tear osmolarity using nanoliter (nL) volumes of tear fluid collected directly from the eyelid margin.

To perform a test, a new Test Card containing a microfluidic capillary channel is attached onto the Pen. The tip of the Test Card is touched to the inferior tear meniscus located above the lower eyelid and collects 40-50 nanoliters of tear fluid by passive capillary action.

After a successful collection, the Pen in conjunction with the electrodes embedded on the Test Card, measures and stores the tear fluid impedance. The Pen is then docked to the Reader.

The Reader downloads impedance data from the Pen in order to calculate and display the final osmolarity as a numerical value displayed in units of mOsms/L.

The TearLab Osmolarity System simplifies the tear collection process by reducing the required specimen volume to nanoliters, eliminating the need to transfer tear fluid and reducing the risk of evaporation.

Principles of the Procedure

The TearLab Osmolarity test utilizes an electrical impedance measurement to provide an indirect assessment of osmolarity. After applying a lot-specific calibration curve, osmolarity is calculated and displayed as a quantitative numerical value.

Section VI
510(k) Summary
Performance
Testing Summary

Precision Studies

Contrived tear specimens distributed across the clinical range of interest[1], 275–400 mOsms/L, were used for performance testing (see Section XIX, Rationale for Use of Contrived Tears during Performance Testing).

1. Single Instrument Precision

Precisions calculated as defined in *CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods.* Tear samples were analyzed over 20 consecutive days

Sample	Average Osmolarity (mOsms/L)	Within Run (SD)	Within Run (CV%)	Total (SD)	Total (CV%)
Low	280	3.8	1.34%	5.2	1.87%
Normal	294	5.5	1.85%	7.3	2.47%
Moderate	316	4.5	1.41%	6.6	2.08%
High	345	4.5	1.30%	8.0	2.33%

2. Between Instrument Precision

One site, five instruments

Sample	Mean Osmolarity	Total (SD)	Total (CV%)
Normal	296	4.9	1.64%
Moderate	316	5.3	1.68%

3. Lot-to-Lot Precision

One site, three lots

Sample	Lot 1	Lot 2	Lot 3	Mean Osmolarity	Total (SD)	Total (CV%)
Low	279	276	277	277	3.8	1.39%
Normal	295	296	291	294	4.9	1.65%
Moderate	307	303	301	304	6.5	2.15%
High	338	326	324	329	7.5	2.28%

4. Between Site Precision

Three sites, three instruments & four lots

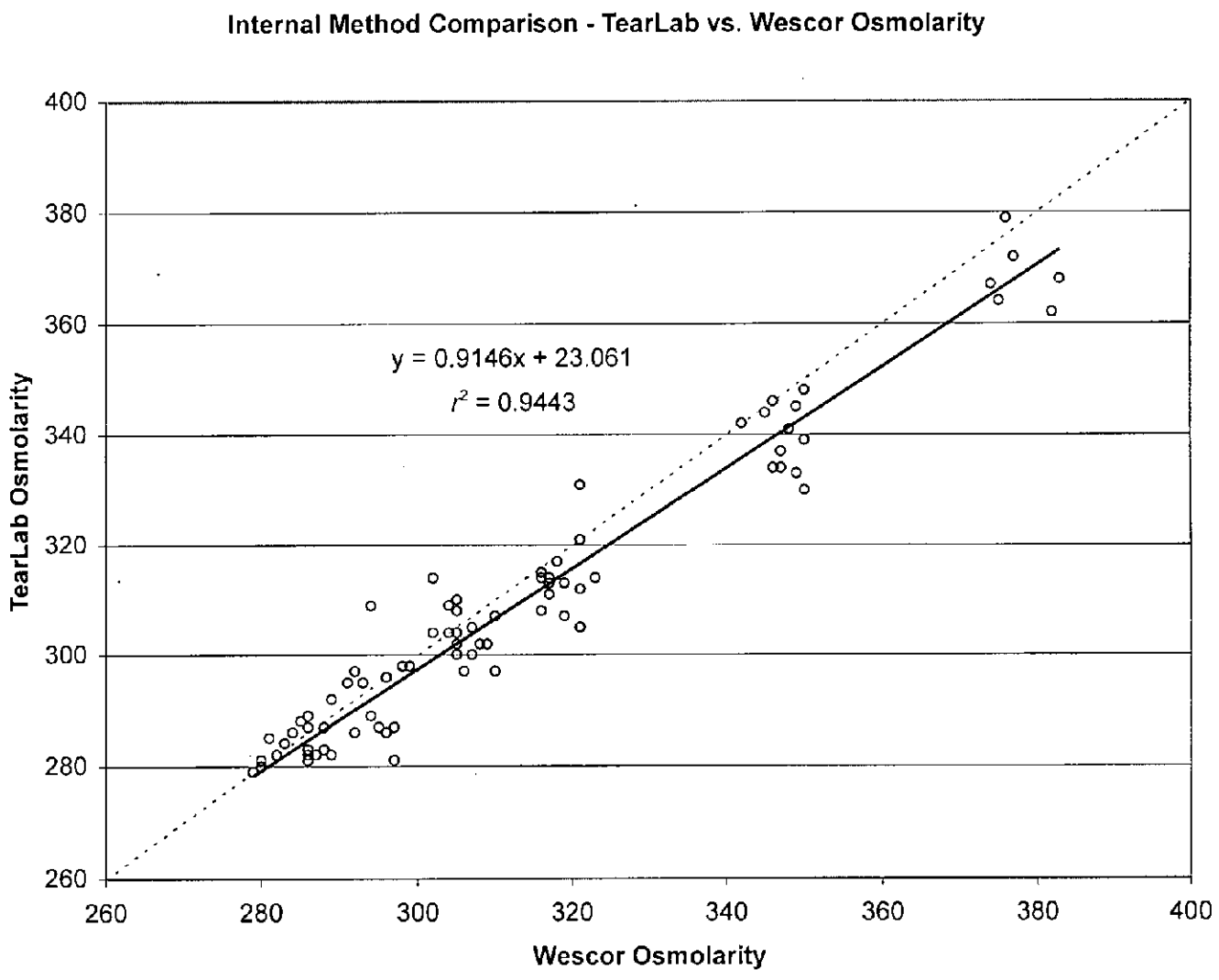
Sample	Average Osmolarity	Total (SD)	Total (CV%)
Low	278	4.4	1.59%
Normal	289	6.0	2.09%
Moderate	308	6.3	2.05%
High	336	8.8	2.61%

Section VI
510(k) Summary
Performance
Testing Summary

Internal Method Comparison

Seven levels of contrived tear solution, distributed throughout the clinically significant range of osmolarity[1], were prepared and measured on the predicate Wescor 5520 Vapro® Osmometer and the TearLab Osmolarity System. The Deming regression between the individual Wescor values (*x*) and individual Tearlab values (*y*) is shown below. The red dotted line represents a line with a slope of 1.0.

Parameter	Coefficient	Std Error	95%CI
Intercept	23.061	8.470	6.201 to 39.920
Slope	0.9146	0.0276	0.8597 to 0.9694
Concordance coefficient	0.9588		
Regression Equation	y = 0.9146x + 23.061		



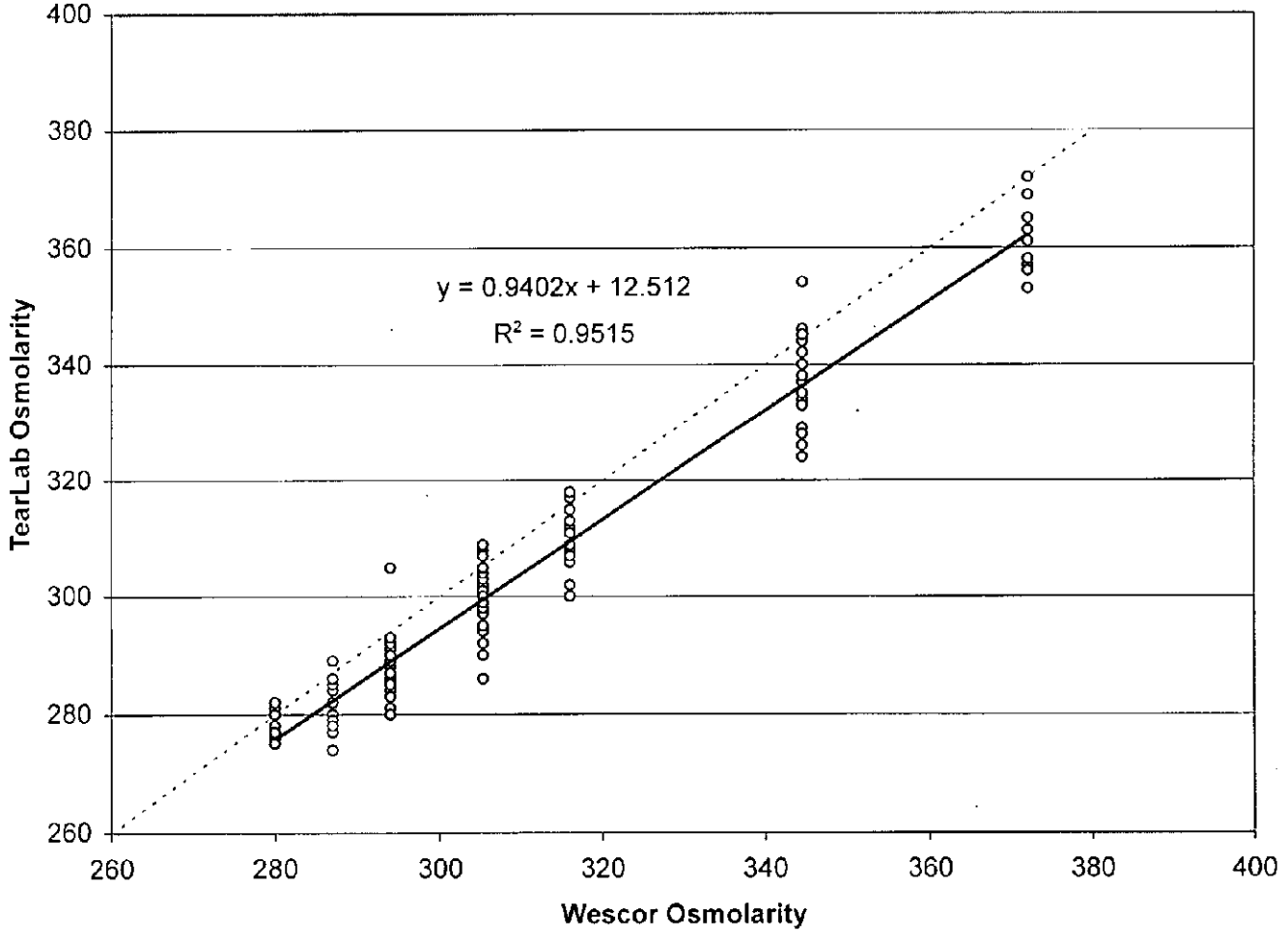
Section VI
510(k) Summary
Performance
Testing Summary

External Method Comparison

At each of three physician office sites, forty contrived tear specimens across seven levels of the clinically significant range were prepared and measured on the TearLab Osmolarity System. The physician office laboratories did not have access to the Wescor 5520 Vapro® vapor pressure osmometer. Wescor values were determined by an average of 2-3 measurements on each level of osmolarity immediately prior to the beginning of the study.

No. sites	N	Regression Line	r^2
3	120	y = 0.9402x + 12.512	0.9515

External Method Comparison - TearLab vs. Wescor Osmolarity



Section VI
510(k) Summary
Performance
Testing Summary

Expected Values & Reference Ranges

Reference tear osmolarity values for normal and dry eye disease patients:
Normal: 288-331 mOsms/L (90% CI 288-331, mean 309.9 ± 11.0)
Dry Eye Disease: 291-382 mOsms/L (90% CI 284-392, mean 324 ± 20.8)
Osmolarity may differ from left and right eye, and each eye should be tested and assessed to determine which eye represents the higher osmolarity.

Calibration Data

To determine clinical performance for tear film hyperosmolarity in the diagnosis of Dry Eye Disease (DED) a meta-analysis was performed on historical published data for tear osmolarity in samples of normal and dry eye subjects. An osmolarity referent 316 mOsms/L was found to yield sensitivity of 69%, specificity of 92%, and an overall predictive accuracy of 82% for the diagnosis of dry eye syndrome. Studies in the meta-analysis used earlier osmolarity devices, not TearLab.

Table 1. Performance of Osmolarity in meta-analysis

	Normal	Dry Eye	Total		
≤ 316	750	192	942	80%	NPV
> 316	65	429	494	87%	PPV
Total	815	621	1,436		
	Specificity	Sensitivity	Accuracy		
	92%	69%	82%		

[Tomlinson A, Khanal S, Ramaesh K, Diaper C, McFadyen A. Tear Film Osmolality: Determination of a Referent for Dry Eye Diagnosis," Investigative Ophthalmology & Visual Science, October 2006; 47(10) 4309-4315]

Performance on patients with objective signs of dry eye

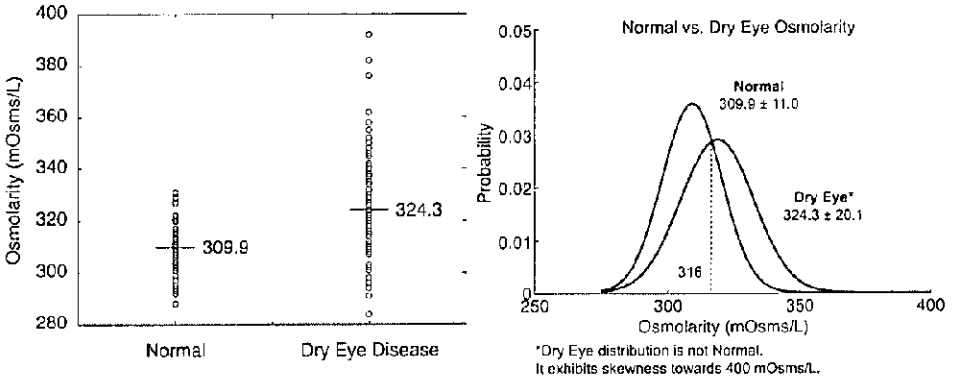
140 subjects were enrolled in a multicenter study (n = 45 Normal, n = 95 Dry Eye). To qualify as a Dry Eye patient, subjects were required a positive score on the Ocular Surface Disease Index (OSDI) and 2 or more positive indications of Tear Film Breakup Time (TBUT), Schirmer Test, Corneal Staining, Conjunctival Staining, or Meibomian Gland Dysfunction. Performance of the TearLab™ Osmolarity System using these selection criteria are shown below in Table 2:

Table 2. TearLab Osmolarity Diagnostic Performance for Dry Eye Disease

	Normal	Dry Eye	Total		
≤ 316	32	34	66	48%	NPV
> 316	13	61	74	82%	PPV
Total	45	95	140		
	Specificity	Sensitivity			
	71%	64%			

Section VI
510(k) Summary
Performance
Testing Summary

Figure 1. Distribution of Osmolarities in Normal and Dry Eye Disease subjects.



Substantial Equivalence

The intended use of the TearLab Osmolarity System, like the predicate Wescor osmometer, is to measure the osmolarity of body fluid. Although the TearLab System is specifically indicated for use in the measurement of osmolarity of human tears, while the Wescor osmometer is indicated for use more generally in body fluids, the indications for use of the Wescor encompass the indications for use of the TearLab. In addition, compared to the other predicate devices, the TearLab System has similar indications for use in assessing human tears as the predicate Schirmer strips and Touch IgE microassay, which are also indicated for evaluation of human tears. The TearLab Osmolarity System has the same technological characteristics as its predicate devices, and any technological differences between the TearLab and the predicates do not raise new questions of safety or effectiveness. Performance data demonstrate that the TearLab is as safe and effective as the Predicate Devices. Thus, the TearLab Osmolarity System is substantially equivalent to other legally marketed tear collection and measurement devices.

1. 275-400 mOsms/L, ref: Tomlinson, A, Khanal, K, Ramaesh, C et al, Diaper et al, Tear Film Osmolarity: Determination of a Referent for Dry Eye Diagnosis. IOVS. 2006;47(10)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 2009

OcuSense, Inc.
c/o Janice M. Hogan
Hogan & Hartson LLP
1835 Market St., 29th Floor
Philadelphia, PA 19103

Re: k083184
Trade/Device Name: TearLab Osmolarity System
Regulation Number: 21 CFR 862.1540
Regulation Name: Osmolality test system
Regulatory Class: Class I
Product Code: OND, JJX
Dated: April 23, 2009
Received: April 23, 2009

Dear Ms. Hogan:

This letter corrects our substantially equivalent letter of May 14, 2009.

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 (if known): k083184

Device Name: TearLab™ Osmolarity System

Indication For Use:

The TearLab Osmolarity System is intended to measure the osmolarity of human tears to aid in the diagnosis of dry eye disease in patients suspected of having dry eye disease, in conjunction with other methods of clinical evaluation.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (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)

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

510(k) K083184