ST 14-0005-PLR 08/12/14 MEDICAL APPLIANCES
Diagnostic equipment does not qualify as a medical appliance. See 86 Ill. Adm. Code 130.311(d)(5). (This is a PLR.)

August 12, 2014

Dear Xxxx:

This letter is in response to your letter dated April 15, 2014, in which you request information. The Department issues two types of letter rulings. Private Letter Rulings ("PLRs") are issued by the Department in response to specific taxpayer inquiries concerning the application of a tax statute or rule to a particular fact situation. A PLR is binding on the Department, but only as to the taxpayer who is the subject of the request for ruling and only to the extent the facts recited in the PLR are correct and complete. Persons seeking PLRs must comply with the procedures for PLRs found in the Department's regulations at 2 Ill. Adm. Code 1200.110. The purpose of a General Information Letter ("GIL") is to direct taxpayers to Department regulations or other sources of information regarding the topic about which they have inquired. A GIL is not a statement of Department policy and is not binding on the Department. See 2 Ill. Adm. Code 1200.120. You may access our website at www.tax.illinois.gov to review regulations, letter rulings and other types of information relevant to your inquiry.

Review of your request disclosed that all the information described in paragraphs 1 through 8 of Section 1200.110 appears to be contained in your request. This Private Letter Ruling will bind the Department only with respect to COMPANY for the issue or issues presented in this ruling, and is subject to the provisions of subsection (e) of Section 1200.110 governing expiration of Private Letter Rulings. Issuance of this ruling is conditioned upon the understanding that neither COMPANY nor a related taxpayer is currently under audit or involved in litigation concerning the issues that are the subject of this ruling request. In your letter you have stated and made inquiry as follows:

> On behalf of our client COMPANY (hereafter referred to as "client"), we are requesting a written advisory opinion pertaining to the sales and use taxability of the TEST PRODUCTS. Our client is requesting this opinion from you in order to better comply with your jurisdiction's tax collection and reporting requirements. We are providing the following facts in regards to the TEST PRODUCTS.
>
> ***Company Description***
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> Our client develops and markets lab-on-a-chip technologies that enable eye care practitioners to improve standard of care by objectively and quantitatively testing for disease markers in tears at the point-of-care. The SYSTEM is the first objective and quantitative test for diagnosing and managing Dry Eye patients.
>
> ***What is Dry Eye Disease?***
>
> Dry Eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.

Tears fulfill an essential role in maintaining ocular surface integrity, protecting against microbial challenge, and preserving visual acuity. These functions, in turn, are critically dependent upon the composition, concentration and stability of the tear film structure. Disruption, deficiency, or absence of the tear film can severely impact the eye. Associated disorders can lead to desiccation of the corneal epithelium, ulceration and perforation of the cornea, an increased incidence of infectious disease, and other clinical conditions.

Hyperosmolarity has been described in the literature as the primary marker of tear film integrity. When the quantity or quality of secreted tears is compromised (known as aqueous deficient or evaporative Dry Eye Disease), increased rates of evaporation lead to a more concentrated tear film (increased osmolarity) that places stress on the corneal epithelium and conjunctiva.

The prevalence of Dry Eye increases with age. In 2011, the American Academy of Ophthalmology (AAO) released in a statement that an estimated 3.2 million women, age 50 and over, and 1.68 million men, age 50 and over, are affected by Dry Eye in the United States alone.

Diagnosis of Dry Eye Disease

Hyperosmolarity has been described in the literature as the primary marker of tear film integrity. When the quantity or quality of secreted tears is compromised (known as aqueous deficient or evaporative Dry Eye Disease), increased rates of evaporation lead to more concentrated tear film (increased osmolarity) that places stress on the corneal epithelium and conjunctiva.

Cure, Mitigation, Treatment, and/or Prevention of Dry Eye Disease

Abnormal tear osmolarity is a failure of homeostatic osmolarity regulation. Elevated osmolarity can cause less regulation of the tear film, more damage to the ocular surface, and more inflammation.

Based on the results of a 300 patient trial that was presented at the 2009 American Academy of Ophthalmology, osmolarity was found to have correctly identified 88% of normal subjects, 75% of mild/moderate disease subjects, and 95% of severe disease subjects at a diagnostic cut-off of 308 mOsms/L. Therefore, osmolarity values above 308 mOsms/L are generally indicative of dry eye disease.

Hyperosmolarity is the only characteristic of dry eye that can be objectively and reliably measured. Osmolarity testing has been declared the “gold standard” of objective dry eye diagnosis, and the single best biomarker of disease severity.

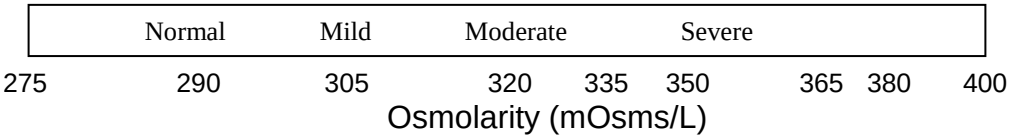
SYSTEM

SYSTEM is the first objective and quantitative test for diagnosing and managing Dry Eye patients.

- Provides fast and accurate results in seconds using only 50 nanoliters (nL) of tear film to diagnose Dry Eye Disease;
- Enables discussion with patients around a number improving compliance;
- Gives the best indication of early stage disease by incorporating osmolarity into the standard of care.
- Improves compliance of patients on care programs.

The SYSTEM is intended to measure the osmolarity of human tears to aid the diagnosis of Dry Eye Disease in patients suspected of having Dry Eye Disease, in conjunction with other methods of clinical evaluation. The TEST PRODUCT, in conjunction with the SYSTEM, provides a quick and simple method for determining tear osmolarity using nanoliter (nL) volumes of tear fluid collected directly from the ocular surface.

The TEST utilizes a temperature-corrected impedance measurement to provide an indirect assessment of osmolarity. A voltage is applied to the tear fluid, and the electrical impedance of the dissolved tear fluid particles is monitored over time. After application of a calibration curve to the steady-state electrical impedance of the tear fluid, osmolarity is calculated and displayed as a quantitative numerical value.



TEST PRODUCTS

The TEST PRODUCT is a single-use, individually packaged, non-sterile, polycarbonate microchip containing (a) a microfluidic channel to collect 50 nanoliters (nL) of tear fluid by passive capillary action, and (b) gold electrodes embedded in the polycarbonate card to enable measurement of the impedance of the tear fluid sample in the microfluidic channel. Each TEST PRODUCT is clinically hygienic and contains a protective cover. TEST PRODUCTS are designed to work in conjunction with the SYSTEM.

TEST PRODUCTS are designed for and intended for single-use only. Two TEST PRODUCTS are used to collect tear fluid samples from both eyes of a patient. After the testing is complete, the TEST PRODUCTS must be discarded, as they cannot be reused.

The following web link provides a more visual presentation of how the TEST PRODUCTS work in conjunction with the SYSTEM.

http://www.XXXXXXXXXXXXXXXX.htm

Question

Are sales of TEST PRODUCTS subject to Illinois sales and use taxes?

Proposed Response

We hereby propose that sales of TEST PRODUCTS are subject to the reduced Illinois sales and use tax rate of 1% based on ILCS Chapter 35 §120/2-5(35-5) as well as Ill. Admin. Code 86§130.311. We are unable to locate any authority that may be contrary to our proposed response.

Please provide any statutory or regulatory guidance related to your ruling where applicable. We also request this private letter ruling not to be published or otherwise make [sic] available to the general public if possible. Thank you in advance for your timely response to this private letter ruling request.

DEPARTMENT'S RESPONSE:

The Department's regulation regarding the appropriate tax rate for medical appliances can be found at 86 Ill. Adm. Code 130.311. Products that qualify as medical appliances are taxed at a lower State rate of 1% plus any applicable local taxes. Those items that do not qualify for the lower rate of tax are taxed at the general merchandise rate of 6.25% plus applicable local taxes.

A medical appliance is an item that directly substitutes for a malfunctioning part of the human body. Included in the list of items that qualify as medical appliances are such items as artificial limbs, dental prostheses and orthodontic braces, crutches and orthopedic braces, wheelchairs, heart pacemakers, and dialysis machines (including the dialyzer), as these products directly substitute for a malfunctioning part of the human body. Corrective medical appliances such as hearing aids, eyeglasses and contact lenses also qualify for the lower State rate.

It is the Department's position, as codified in its regulation at 86 Ill. Adm. Code 130.311(d)(5), that diagnostic equipment is not a medical appliance. Based on the information you provided in your letter, the Department has determined that the TEST PRODUCTS which are designed to work in conjunction with the SYSTEM are part of diagnostic equipment and, thus, are not a medical appliance. Accordingly, TEST PRODUCTS do not qualify for the lower State rate of tax and would be taxed at the general merchandise rate of 6.25% plus applicable local taxes.

The factual representations upon which this ruling are based are subject to review by the Department during the course of any audit, investigation, or hearing and this ruling shall bind the Department only if the factual representations recited in this ruling are correct and complete. This Private Letter Ruling is revoked and will cease to bind the Department 10 years after the date of this letter under the provisions of 2 Ill. Adm. Code 1200.110(e) or earlier if there is a pertinent change in statutory law, case law, rules or in the factual representations recited in this ruling.

I hope this information is helpful. If you have further questions concerning this Private Letter Ruling, you may contact me at 782-2844. If you have further questions related to the Illinois sales tax laws, please visit our website at www.tax.illinois.gov or contact the Department's Taxpayer Information Division at (217) 782-3336.

Very truly yours,

Richard S. Wolters

Chairman, Private Letter Ruling Committee

RSW:DMB:lkm