

Ocular Imaging Research and Reading Center

Device Certificate

Certificate Id: OIRRC-01-a4dbfe89-O
Transmission Numbers: 20210310-074622443
Issue Date: Apr 15, 2021
Valid until: Apr 15, 2025

A Phase III, Multicenter, Sham-Controlled, Randomized, Double-Masked Study Assessing the Efficacy and Safety of Intravitreal Injections of 440 µg DE-109 for the Treatment of Active, Non-Infectious Uveitis of the Posterior Segment of the Eye

Sponsor: Santen Pharmaceuticals Inc.

Site: Texas Retina Associates - Arlington
Address: 801 West Randol Mill Road, Arlington, TX, United States
Site Code: USA132

Device Information	
Device Modality	Optical Coherence Tomography
Device Manufacture	Optos, Inc.
Device Model	200TX
Device Serial Number	860-11510
Software Version	1.5.1.78

The sample images submitted to the OIRRC (transmission # 20210310-074622443) relevant to the abovementioned device are compliant with requirements and standards of **The LUMINA Trial** imaging manual. The Ocular Imaging Research and Reading Center (OIRRC) is hereby issuing a certificate for the above-mentioned device for the use to obtain images in the **The LUMINA Trial** study.

This certificate is valid for **4 years** from the time it is issued provided that no major modifications, upgrades, updates, or repairs are made during that period. It is the responsibility of the PI and the study team at the Study Site to maintain the integrity of the certification status of the above- mentioned device. Please, communicate with the OIRRC regarding such modifications or other conditions that can possibly affect or compromise the certification status of the device.

Certification Officer



26/03/2021

Super Admin