Ocular Imaging Research and Reading Center

Device Certificate

Certificate ID: OIRRC-01-35730078-G

Transmission Number(s): 20210310-074145870

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: MedEye Associates

Address: 5858 Southwest 68th Street, South Miami, FL, United States

Site Code: USA113

0	Device Information
Device Modality	Modified 3 Fields Color Fundus Photography
Device Manufacture	Optos, Inc.
Device Model	P200DTx
Device Serial Number	H2E-24949-008-001
Software Version	1.10.4.0

The sample images submitted to the OIRRC (transmission # 20210310-074145870) 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

03/31/2021

Super Admin