

FDA Clears Gyroscope Therapeutics' Subretinal Delivery System

August 25th, 2020 – Gyroscope Therapeutics Limited, a clinical-stage retinal gene therapy company, announced that the FDA has granted 510(k) clearance for the Orbit Subretinal Delivery System.



The Orbit SDS is indicated for microinjection into the subretinal space at the back of the eye. The approach avoids damaging the structure of the eye by preventing the need for a vitrectomy and eliminates the need to create a retinotomy to access the subretinal space. The Orbit SDS is capable of delivering a controlled volume to a targeted subretinal delivery site. The Orbit SDA accesses the subretinal space via a suprachoroidal approach, enabling cannulation of the suprachoroidal space with a flexible cannula.

“Our mission is to develop gene therapies and delivery systems to help preserve sight and fight the devastating impact of blindness. The FDA clearance of the Orbit SDS is an important component in advancing toward this goal.”
--Khurem Farooq, Chief Executive Officer

The clearance authorizes the company to market and sell the Orbit SDS in the United States. In addition to developing the Orbit SDS for its own investigational medicines.

Gyroscope plans to enter into licensing

and collaboration arrangements involving the Orbit SDS with other companies who are developing gene and cell therapies to treat eye disease.

Gyroscope Therapeutics is a clinical-stage retinal gene therapy company developing and delivering gene therapy beyond rare disease to treat a leading cause of blindness, dry age-related macular degeneration. Headquartered in London with locations in Philadelphia and San Francisco, their mission is to preserve sight and fight the devastating impact of blindness.

