

Optical Module FDA



Overview

The FDA has cleared the SPECTRALIS Flex Module (Heidelberg Engineering), an innovative diagnostic platform designed to enhance access to multimodal imaging for patients unable to use traditional tabletop OCT devices, according to a press release. The Center for Devices and Radiological Health (CDRH) is the FDA center responsible for overseeing the radiation-emitting products program. (Photo: Business Wire) FRANKLIN, Mass. -- (BUSINESS WIRE)-- Heidelberg Engineering, a global leader in ophthalmic. Heidelberg Engineering GmbH announced that the FDA has granted 510 (k) clearance for the SPECTRALIS Optical Coherence Tomography-Angiography (OCTA) Module with SHIFT technology, designed to significantly reduce imaging acquisition time. This multimodal, diagnostic imaging-only platform is designed for. The SPECTRALIS with Flex Module is an advanced eye imaging device designed for non-contact visualization of the posterior segment and vasculature of the retina and choroid in adults and pediatric patients, including those in supine (lying down) position. It helps ophthalmologists detect and monitor.



Article Content

FDA Grants Clearance for SPECTRALIS Flex Module, Expanding

FRANKLIN, Mass.-- (BUSINESS WIRE)-- Heidelberg Engineering, a global leader in ophthalmic imaging and healthcare data solutions, announces FDA clearance of the SPECTRALIS ®

FDA clears Heidelberg Engineering's SPECTRALIS

Heidelberg Engineering GmbH announced that the FDA has granted 510 (k) clearance for the SPECTRALIS Optical Coherence Tomography

FDA clears SPECTRALIS Flex module for advanced ophthalmic imaging

The FDA has cleared the SPECTRALIS Flex Module (Heidelberg Engineering), an innovative diagnostic platform designed to enhance access to multimodal imaging for patients unable to use traditional

FDA Grants Clearance for Heidelberg's SPECTRALIS Flex Module

Heidelberg Engineering announced FDA clearance of the SPECTRALIS Flex Module. This multimodal, diagnostic imaging-only platform is designed for imaging the posterior segment of

SPECTRALIS with Flex Module | FDA Radiology AI Device

The SPECTRALIS with Flex Module is an advanced eye imaging device designed for non-contact visualization of the posterior segment and vasculature of the retina and choroid in adults

FDA Grants Clearance for SPECTRALIS Flex Module

“Receiving FDA clearance for the SPECTRALIS Flex Module fulfills our vision of bringing Heidelberg image quality to all patients, regardless of their

SPECTRALIS Flex Module Receives FDA Clearance, Expanding

Heidelberg Engineering announced FDA clearance of the SPECTRALIS Flex Module, a multimodal diagnostic imaging platform designed for posterior segment imaging in pediatric and adult

Heidelberg Engineering Receives FDA Clearance for Spectralis Flex ...

The new module is designed specifically for imaging the posterior segment of both pediatric and adult patients in a supine position, addressing a need for patients unable to use

China's Vivolight Secures First-Ever US FDA Approval for a

(Yicai) April 16 -- The multimodality optical coherence tomography systems developed by Chinese healthcare solutions provider Vivolight Medical Device and Technology have become the first ever to

FDA clears Heidelberg Engineering's SPECTRALIS

Heidelberg Engineering GmbH has received FDA 510 (k) clearance for the SPECTRALIS Flex Module, a multimodal diagnostic imaging platform.

HHS Publication FDA 86-8260

r or vary the attenuation. Viewing optics include such devices as viewports, windows, microscopes on welding and drilling devices, and operating mic scopes on surgical lasers. Attenuation may be ...

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