Indications for Use

510(k) Number (if known): K023525

Device Name: RETIscan RETIport

Indications For Use: Electrophysiological Test Unit for quantifying the retinal response, measuring a parameter (VEP) related to retinal response

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K023525

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)