Alcon

LenSx

COVER LETTER

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Alcon LenSx, Inc.

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Aliso Viejo, CA 92656

The LenSx Laser System is an ophthalmic surgical laser for use in cataract and corneal surgery. The laser system uses a sterile, single use medical device for the patient interface. Each patient interface is instrumented with a passive RFID tag that uniquely identifies each interface. LenSx Laser system authenticates each RFID tag to initiate a surgical treatment and to prevent re-use of the patient interface. The laser system (host) integrates the low power Skyetek SkyeModule M2 and antenna hardware for RFID detection. The laser system communicates to the M2 Module via RS-232 and provides a regulated +5V for power. The antenna is located at the laser system suction port for the patient interface. The effective range for the RFID tag is approximately 100mm.

There are no user/operator interactions with RFID radio settings. All functions are handled via the host system and are pre-set at the factory.

The RFID device is used at a single power mode and frequency of 13.56 MHz.

RFID Manufacturer: SkyeTek:

- SkyeTek Module Number: SM-M2-MH-HF
- SkyeTek HF Antenna Module Number: SP-AN-04-HF-CBLC

Testing and equipment approvals for the LenSx Laser System RFID:

- NorthWest EMC (Irvine, CA.) performed all of the testing and report writing to the following standards (Class A).
    - FCC 15.225:2010
    - RSS-210:2007
    - International:
        - EN 300 330-2 V1.3.1:2006
        - AS/NZS 4268:2008
- NorthWest EMC (Irvine, CA.) performed the Radiated (10meter) site testing portion of the EN/IEC 60601-1-2 and was found to comply.
- Intertek Testing Services (Lake Forest, CA.) performed the medical device testing and report writing to EN/IEC 60601-1-2 (Class A) standards for Radiation and Immunity and was found to comply.

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