DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K190420

Device Name
NDŌHD High Definition Imaging System (NDŌHD)

Indications for Use *(Describe)*

The NDŌHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic procedures. The professionals or practitioners using this system would be medical doctors or clinicians such as speech pathologists. The device is a prescription device. The NDŌHD system is not intended to be used in an environment that requires sterilization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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