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)*
K190729

Device Name
SPY Portable Handheld Imaging (SPY-PHI) System

Indications for Use *(Describe)*
Upon intravenous administration of SPY AGENT™ GREEN (Indocyanine green for injection, USP) the SPY-PHI System is used with SPY AGENT™ GREEN in capturing and viewing fluorescence images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.

The SPY-PHI System is used with SPY AGENT™ GREEN to provide fluorescence images for the visual assessment of blood flow in vessels and related tissue perfusion before, during and after gastrointestinal surgical procedures.

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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