

K230727 SPY Portable Handheld Imaging (SPY-PHI) SystemJun 5, 2023
81 days to decisionK230727 · Product code: IZI · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k230727/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Mar 16, 2023
Decision date	Jun 5, 2023
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Novadaq Technologies Ulc (A Part of Stryker)
Location	Burnaby, CA
Contact	Cara Cahill
510(k) history	1 submissions · 1 cleared · 2023-2023

CLINICAL EVIDENCE - NCT03200704**A Study Assessing the Safety and Effectiveness of IC2000 and SPY Fluorescence Imaging Systems (SPY-PHI) in the Visualization of Lymphatic Vessels and Identification of Lymph Nodes During Sentinel Lymph Node Biopsy in Subjects With Breast Cancer**

Status	Completed
Enrollment	152 patients (actual)
Study sites	7 sites
Condition studied	Breast Cancer; Lymph Node Mapping; Sentinel Lymph Node Biopsy
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Sep 28, 2020
Sponsor	Novadaq Technologies ULC, now a part of Stryker (Industry)

Primary outcome

Proportion of Lymph Nodes Identified by IC2000/SPY-PHI Compared to the Proportion of Lymph Nodes Identified by Tc99m/Gamma Probe

Secondary outcome

Proportion of Subjects With at Least One Lymph Node Identified by IC2000/SPY-PHI, and the Proportion of Subjects With at Least One Lymph Node Identified by Tc99m/Gamma Probe

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03200704