

Brand Name or Equal Worksheet (“Salient Characteristics”) v 2.0

Brand Name Item: Boston Scientific- SpyGlass DS System

1) Essential/significant physical, functional, or performance characteristics.

SpyGlass DS System:

- Must be able to determine if patient has cancer of the bowel ducts, pancreatic cancer, or gallstones
- Must be able to help drain cysts, remove bowel duct stones, pancreatic duct stones, and diagnose strictures
- Must fit on a standard endoscopy cart
- Must have an integrated digital sensor
- Single use scope with tapered catheter tip
- Same unit for camera and light source
- Set-up time under 5 minutes
- Must have a fixed imager for consistent steering
- Generator:
 - Automatic power range regulation to prevent overload to the probe
 - Automatic probe monitoring and alerts for when to replace the probe
 - Touch screen controls to make it easy to use and understand
- Probe:
 - 1.9 Fr., 375 cm
- Digital Controller:
 - Automatic light control and LED illumination
 - Dedicated irrigation and aspiration channels
 - Automatic white balance and focus
- Forceps:
 - 1 mm outer diameter
 - 4.1 mm biopsy cup opening
 - Central spike to help secure samples

2) Complete generic identification – Bipolar Electrohydraulic Lithotripsy System

3) Applicable model/make/catalog number –

M005466800 Autolith Touch EHL Generator

M00546650 SpyGlass™ DS - Digital Controller

M00546600 SpyScope Digital Access and DeliveryCath

M00546620 Autolithtouch EHL Probe SpyGlass DS

M00546270 Spybite Biopsy Forceps

4) Manufacturer name – Boston Scientific

Per VAAR 811.104 and 811.105, I certify the following regarding the above information:

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- The salient characteristics listed above are essential to the Government’s requirements.
- To my knowledge, the restrictions listed above will not limit the acquisition to an item peculiar to one manufacture.

Name, Date: Jason Lee

Madison Pallante

6/13/18