***Envisioned Product Intake Form***

This information will be used for constructing target product profiles to be used in primary market research interviews, competitive landscape assessments, regulatory roadmaps, and reimbursement assessments.

|  |  |
| --- | --- |
| **Description of Device**  | * What it is
* What it does
 |
| **Clinical Indications For Use / Statement of Intended Use** |  |
| **Process For Using Device** | * General description
 |
| **Anticipated Outcomes** |  |
| **Anticipated Safety** |  |

|  |
| --- |
|  |
| **TECHNOLOGY/ DEVICE** |
| 1. What are the major components of the envisioned device, and function of each component?
2. Is technology a stand alone device or part of a system?
 |
| 1. What equipment will be required to use device?
 |
| 1. What supplies will be used in conjunction with device?
 |
| 1. Will device be single use or reusable?
 |
| 1. Will there be future generations or additional indications for use? Please explain.
 |
|  |
| **PROCEDURE/SERVICE** |
| 1. What is the purpose of the procedure? (To diagnose, to treat?)
 |
| 1. What type of health care provider will provide the service? (physician-specify all specialties involved, nurse, lab tech, ultrasound tech, dietician, etc.)
 |
| 1. What body part is being worked on? (Be specific, if it is the urethra, what section of the urethra is involved? e.g., prostatic, bulbar?) (If blood, which components of the blood?)
 |
| 1. What is the sequence of events leading to the treatment? Example: Pt has pancreatic cancer [tumor growth]. The tumor growth puts pressure on ureter and causes it to obstruct [extrinsic obstruction]. The obstruction is the condition requiring the treatment.
 |
| 1. Obtain step by step outline of procedure. Outline should include:
* Action the physician is doing (incising, excising, ablating, fulgurating, destroying, inserting, implanting, removing, replacing, repairing, etc.)
* Energy source used (laser, electrosurgical generator, ultrasound, etc.)
* Approach physician is taking (endoscopic, percutaneous, open surgery, laparoscopic, etc.)
* Instruments or equipment being used (lithotriptor, laser, fluoroscope, endoscope, etc.)
* Device or supplies being used (implantable stents, implantable prosthesis, balloon dilator, stone baskets, laser fiber—include average number used per procedure if known)
* Number and duties of health care professionals involved with procedure
 |
|  |
| **ASSOCIATED PRODUCTS/SERVICES** |
| 1. Associated services, tests needed intraoperatively (MRI, CTs, x-ray, lab)
 |
| 1. Required pre-procedure testing/associated services
 |
| 1. Required post-procedure testing/associated services
 |
| 1. Specify when the pre and post-op services are being done, e.g. within 72 hours of hospital admission
 |
|  |
| **SITE OF SERVICE (Where will the procedure/service be performed?--list all that apply.)** |
| 1. Hospital inpatient
 |
| 1. Hospital outpatient
 |
| 1. Ambulatory Surgery Center
 |
| 1. Physician Office
 |
| 1. Skilled Nursing Facility
 |
| 1. Home Care
 |
| 1. Other
 |
|  |
| **DIAGNOSTIC/TREATMENT ALTERNATIVES** |
| 1. How is condition/disease currently being diagnosed/treated? (Include watchful waiting if appropriate)
 |
| 1. What are the treatment alternatives and how will they compare to your technology? (According to the literature)
* Effectiveness
* Complications
* Resource consumption
 |
|  |
| **DIRECT COMPETITION/ POTENTIAL PREDICATE DEVICES** |
| 1. Who else is working on/has similar technology?
 |
| 1. How is your technology similar/ different compared to the competition?
 |
|  |