De Novo Program

November 4, 2014

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Learning Objectives

- Describe the legal and regulatory basis for the *de novo* program
- Describe the *de novo* submission process
- Assemble the materials that will lead to a good quality *de novo* submission
- Identify the resources useful in preparing a *de novo*

What is a *de novo*?

A classification process:

- using a risk-based strategy
- for new, novel devices whose type has not previously been classified
- would be classified into Class III
- to classify into Class I or II

What is a *de novo*?

- an application sent by the medical device sponsor to FDA
- if granted:
  - establishes new "device type" along with classification, regulation, necessary controls and product code
  - device is eligible to serve as a predicate for new medical devices, where appropriate [510(k) process]

Federal Food, Drug, and Cosmetic Act (the FD&C Act)

Medical Device Amendments, 1976

Section 513

- classification of medical devices
- risk-based approach:
  - 513(a)(1)(A): Class I, “General Controls”
  - 513(a)(1)(B): Class II, “Special Controls”
  - **513(a)(1)(C):** Class III, “Premarket Approval”

Reference

Regulatory Controls (General, Special , PMA)

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm

FD&C Act

Medical Device Amendments (1976)

Section 513(a)(1)(C)

- Class III, require Premarket Approval
- devices with highest risk
- unable to rely on general and/or special controls

FD&C Act

Medical Device Amendments (1976)

Section 513(f)(1): "new devices"

- post-Amendments Class III devices
- a device not equivalent to a Class I or II device is classified into Class III: a "new device"
- **regardless of risk**

FD&C Act – modified in 1997

Food and Drug Administration Modernization Act (FDAMA)

Section 513(f)(2): established ***de novo*** classification process

- also known as "Evaluation of Automatic Class III Designation"
- provided regulatory authority for FDA to classify devices that were automatically classified into Class III per Section 513(f)(1) (new devices)
- to Class I or II using criteria of Section 513(a)(1)(A-B)

➢ **excludes** devices already classified into Class III

(e.g., PMA-approved devices)

De Novo Process, 1997

1. Sponsor submits premarket notification (510(k))
2. FDA issues final 510(k) decision of "not substantially equivalent" due to no predicate
3. Sponsor submits *de novo* request
4. FDA decides whether to classify device from Class III to Class I or II with new classification/regulation

FD&C Act – further modified in 2012

Food and Drug Administration Safety and Innovation Act (FDASIA)

Section 513(f)(2) – *de novo* provision

What changed

- allowed alternative pathway that doesn't require submission of a 510(k) prior to *de novo* request
- timeframe for review set at 120 FDA days

➢ **goal: to streamline and increase efficiency in process**

FD&C Act – further modified in 2012

Food and Drug Administration Safety and Innovation Act (FDASIA)

Section 513(f)(2) – *de novo* provision

What didn't change

- still only applies to Section 513(f)(1) **(new devices)**
- sponsor may still submit 510(k) first (e.g., FDAMA pathway an option)
- intent and decision-making threshold for *de novo* eligibility unchanged

De Novo Process, effective 2012

1. Sponsor submits *de novo* request

2. FDA decides whether to classify device from Class III to Class I or II with new classification/regulation

1998 *De Novo* Guidance, final

New Section 513(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff

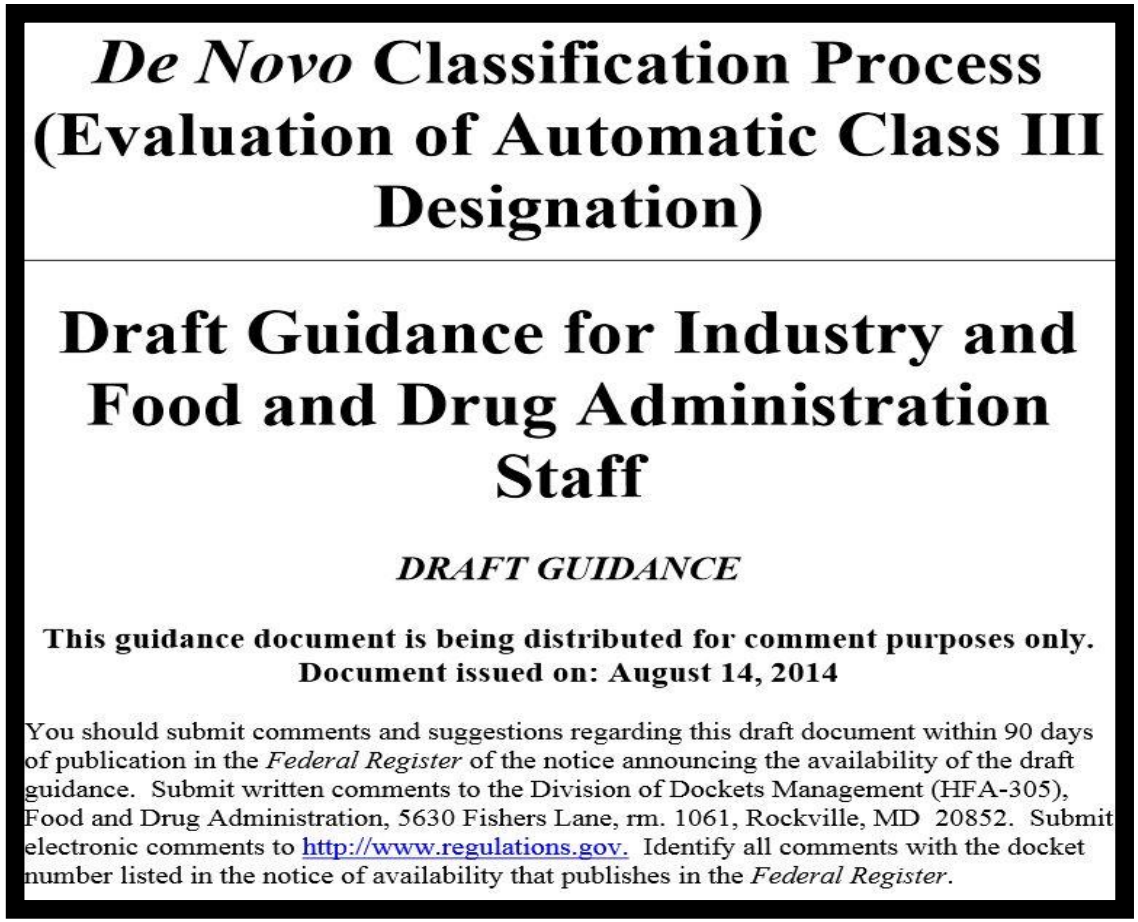
This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Office of Device Evaluation

Document issued on: February 19, 1998

Note: Due to enactment of FDASIA 2012, some aspects of this guidance may no longer be current.

2014 *De Novo* Guidance, draft



De Novo Classification Process (Evaluation of Automatic Class III Designation)

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: August 14, 2014

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

Reference

February 1998 Final Guidance

- http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080197.pdf

August 2014 Draft Guidance

- http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm273903.pdf

2014 *De Novo* Guidance, draft

- published August 14, 2014
- reflects proposed policy and procedures to implement changes to *de novo* program from FDASIA 2012
- **draft guidance**:
  - not implemented at this time
  - if finalized, will replace 1998 Guidance
  - 90-day public comment period

2014 *De Novo* Guidance, draft

Major Items

- explains changes to FD&C Act:
  - allowed alternative pathway that doesn't require submission of a 510(k) prior to de novo request
  - timeframe for review set at 120 FDA days
- Decision Options: **grant** or **decline**
- Pre-Submission meeting process
- new term: "**direct *de novo***" (no 510(k) prior to *de novo* submission)

De Novo Submission Process

Submission Process:
Two Pathways

Pathway #1: 510(k) ➔ *de novo*

- attempt 510(k) route with proposed predicate device
- submission found NSE, but candidate for *de novo*

Pathway #2: direct *de novo*

- useful if you believe proposed device is viable *de novo* candidate (esp. with feedback from Pre-Sub program)

Submission Process:

Pathway #1: 510(k) → *de novo*

- **When to use: You believe you have a suitable predicate device.**

1. **Sponsor submits 510(k) submission**
   - this should be a complete 510(k) submission

Submission Process:

Pathway #1: 510(k) ➔ *de novo*

2. FDA reviews 510(k) submission; makes NSE finding due to lack of predicate

- **lack of predicate** = proposed predicate device does not have same intended use and technological characteristics as new device.
- FDA may choose to indicate in NSE letter that new device may be appropriate *de novo* candidate (based on risk-benefit profile, not adequacy of data submitted)
  - ➢ **the suggestion for *de novo* is not binding**

Submission Process:

Pathway #1: 510(k) → *de novo*

3. Sponsor submits de novo application

- reference prior 510(k)
- provide additional evidence to demonstrate safety and effectiveness of new device, as appropriate
- address any differences and evidence gaps between 510(k) device and *de novo*: provide added testing, S&E information as needed

Submission Process:

Pathway #1: 510(k) → *de novo*

3. Sponsor submits *de novo* application:

- characterize **risks to health** associated with use of new device
- characterize how the risks may be **mitigated**
- provide **rationale** for why device does not fit into an existing regulation
- if propose Class II classification, then identify the **special controls** to mitigate the risks to health

Submission Process:

Pathway #1: 510(k) → *de novo*

4. FDA reviews *de novo* application

- may interact with sponsor, ask for additional information
- render final de novo decision: **grant** or **decline**

Submission Process:

Pathway #2: direct *de novo*

- **When to use:**

1. **You believe you don't have a suitable predicate device either based on your own assessment or through FDA feedback AND**

2. **You believe the device may be classified into Class I or II per *de novo*.**

Submission Process:
Pathway #2: direct *de novo*

1. **Sponsor submits *de novo* application:**
   - evidence that establishes reasonable assurance of safety and effectiveness of new device
     - most information typically submitted in traditional 510(k) submission
     - device description
     - labeling
     - performance testing (bench, animal, clinical)

Submission Process:

Pathway #2: direct *de novo*

1. **Sponsor submits *de novo* application**:
   - characterize **risks to health** associated with use of new device
   - characterize how the risks may be **mitigated**
   - provide **rationale** for why device does not fit into existing regulation (either 510(k) or PMA)
   - if propose Class II classification, then identify the **special controls** to mitigate the risks to health

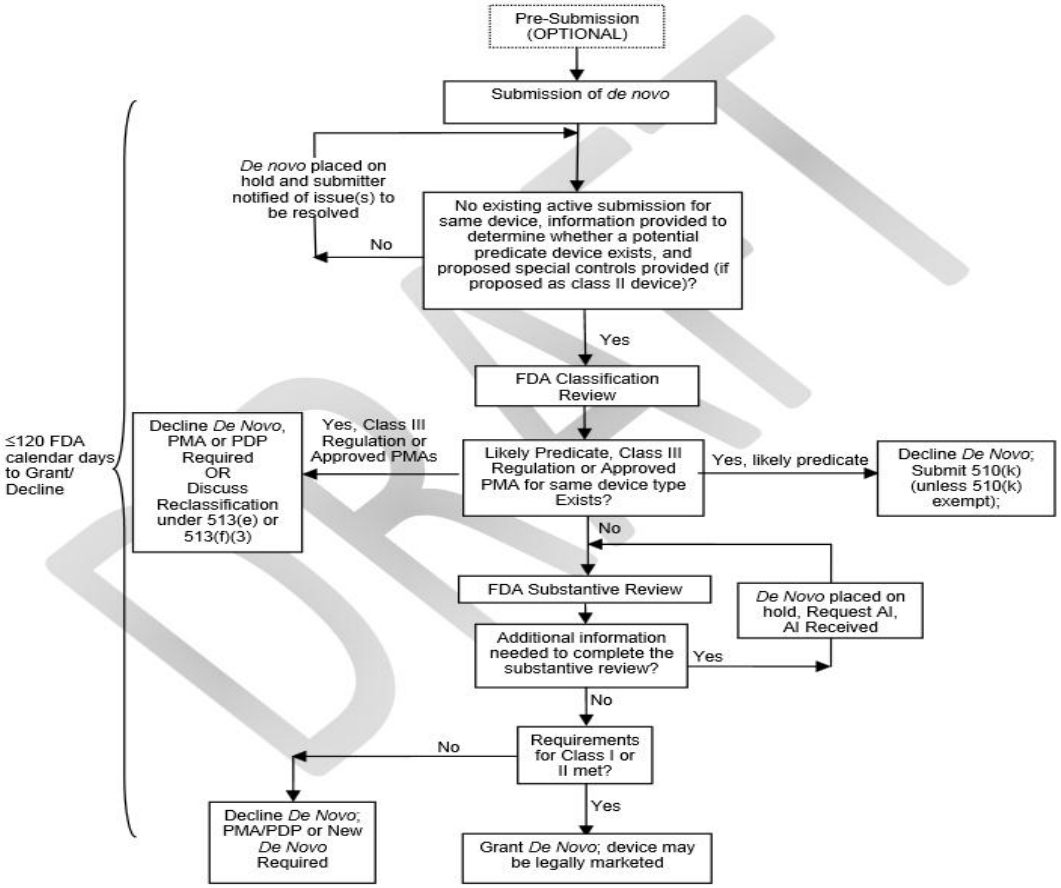
Submission Process:
Pathway #2: direct *de novo*

2. FDA reviews *de novo* application

- may interact with sponsor, ask for additional information
- render final *de novo* decision: **grant** or **decline**

2014 *De Novo* Guidance, draft

New Flowchart



Getting Informal Feedback:
Pre-Sub

FDA strongly encourages sponsors to use Pre-Sub program for potential *de novos*!

- after device design and intended use are established
- after sufficient information has been collected regarding safety and effectiveness (e.g., test methods)
- useful for novel devices with no FDA regulatory history, based on your research

Reference

Pre-Submission Program Guidance

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm

What happens after a *de novo* is granted?

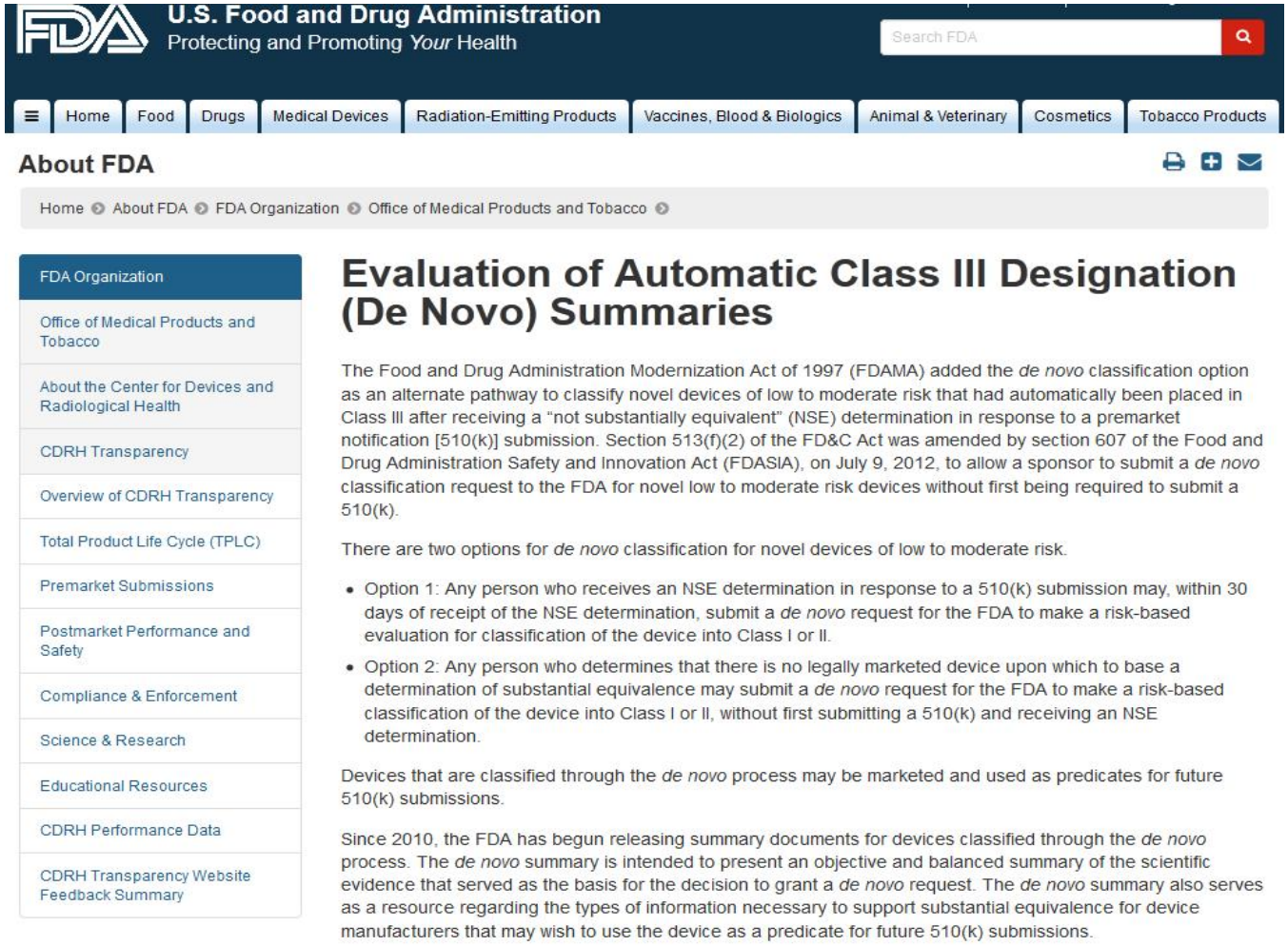
After *de novo* is granted

- **New Device is Legally Marketed**
  - subject to post-market requirements applicable to that device and class (including general controls, special controls as applicable)
- **New Device Establishes New Classification Regulation**
  - new device is eligible to serve as a predicate for future similar devices
    - follows standard 510(k) process

After *de novo* is granted

- FDA publishes order announcing new classification, controls
- FDA generates decision summary that is publicly available

After *de novo* is granted



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Evaluation of Automatic Class III Designation (De Novo) Summaries

The Food and Drug Administration Modernization Act of 1997 (FDAMA) added the *de novo* classification option as an alternate pathway to classify novel devices of low to moderate risk that had automatically been placed in Class III after receiving a "not substantially equivalent" (NSE) determination in response to a premarket notification [510(k)] submission. Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA), on July 9, 2012, to allow a sponsor to submit a *de novo* classification request to the FDA for novel low to moderate risk devices without first being required to submit a 510(k).

There are two options for *de novo* classification for novel devices of low to moderate risk.

- Option 1: Any person who receives an NSE determination in response to a 510(k) submission may, within 30 days of receipt of the NSE determination, submit a *de novo* request for the FDA to make a risk-based evaluation for classification of the device into Class I or II.
- Option 2: Any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may submit a *de novo* request for the FDA to make a risk-based classification of the device into Class I or II, without first submitting a 510(k) and receiving an NSE determination.

Devices that are classified through the *de novo* process may be marketed and used as predicates for future 510(k) submissions.

Since 2010, the FDA has begun releasing summary documents for devices classified through the *de novo* process. The *de novo* summary is intended to present an objective and balanced summary of the scientific evidence that served as the basis for the decision to grant a *de novo* request. The *de novo* summary also serves as a resource regarding the types of information necessary to support substantial equivalence for device manufacturers that may wish to use the device as a predicate for future 510(k) submissions.

Resource

FDA Transparency Website

www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm232269.htm

After *de novo* is granted

Links to all available *de novo* summary documents can be found in the table below.

Device Name	File Number	Classification Order	Decision Summary
Xpert MTB/RIF Assay	K131706	Classification Order	Decision Summary
ReWalk™	K131798	Classification Order	Decision Summary
Prostate Immobilizer Rectal Balloon	K132194	Classification Order	Decision Summary
EUROIMMUN Anti-PLA2R IFA	K132379	Classification Order	Decision Summary
IOGYN System	K132695	Classification Order	Decision Summary
MiSeqDx Universal Kit 1.0	K133136	Classification Order	Decision Summary
Lyra™ Direct HSV 1 + 2/VZV Assay	K133448	Classification Order	Decision Summary
Simplexa™ HSV 1 & 2 Direct	K133621	Classification Order	Decision Summary
Lyra Direct Strep Assay	K133883	Classification Order	Decision Summary
STUDIO on the Cloud Data Management Software	K140016	Classification Order	Decision Summary

Classification Order (pages 1, 3)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 13, 2013

NeoTract, Inc.
% Nancy E. Isaac, JD, MPH
Vice President, Clinical Affairs,
Regulatory Affairs and Quality
4473 Willow Road, Suite 100
Pleasanton, CA 94588

Re: K130651
NeoTract UroLift® System, Model REF UL400
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 876.5530
Regulation Name: Implantable transprostatic tissue retractor system
Regulatory Classification: Class II
Product Code: PEW
Dated: March 6, 2013
Received: March 7, 2013

Dear Ms. Isaac:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the NeoTract UroLift® System, a prescription device under 21 CFR Part 801.109 that is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 50 and above. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the NeoTract UroLift® System, and substantially equivalent devices of this generic type, into class II under the generic name, implantable transprostatic tissue retractor system.

FDA identifies this generic type of device as:

> An **implantable transprostatic tissue retractor system** is a prescription use device that consists of a delivery device and implant. The delivery device is inserted transurethrally and deploys the implant through the prostate. It is designed to increase prostatic urethral patency by providing prostate lobe tissue retraction while preserving the potential for future procedures and is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976

Table 1 - Potential Risks and Mitigations

Identified Risk	Mitigation Measure
Adverse Tissue Reaction to the Device	1. Biocompatibility Testing 2. *In Vivo* Testing
Infection Due to Presence of Foreign Body	1. Sterilization Validation 2. Labeling (including expiration dating) 3. Shelf life testing
Migration of Implanted Device	1. *In Vivo* Testing 2. MR Compatibility Testing
Failure to Deploy Device or Misdeployment	1. Non-clinical Testing 2. *In Vivo* Testing 3. Labeling
Failure of Implanted Device	1. Non-clinical Testing (Mechanical) 2. Non-clinical Testing (Resistance to Degradation) 3. Shelf life testing 4. *In Vivo* Testing 5. Labeling
Improperly Placed Implants	1. *In Vivo* Testing 2. Labeling
Occurrence of Genito-Urinary Adverse Events	1. *In Vivo* Testing 2. Labeling
Presence of Implants Adversely Affects Subsequent Interventions	1. Non-clinical Testing 2. *In Vivo* Testing 3. Labeling

In addition to the general controls of the FD&C Act, the *implantable transprostatic tissue retractor system* is subject to the following special controls:

1. The elements of the device that may contact the patient must be demonstrated to be biocompatible.
2. Performance data must demonstrate the sterility of the patient-contacting components of the device.
3. Performance data must support shelf life by demonstrating continued sterility of the device (of the patient-contacting components), package integrity and device functionality over the requested shelf life.
4. Non-clinical testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   a. Deployment testing must be conducted
   b. Mechanical strength must be conducted
   c. Resistance-to-degradation testing must be conducted

Decision Summary (1st 2 pages)

De Novo Classification Request for Neotract's UroLift System

Regulatory Information

FDA identifies this generic type of device as:

Implantable Transprostatic Tissue Retractor System. An implantable transprostatic tissue retractor system is a prescription use device that consists of a delivery device and implant. The delivery device is inserted transurethrally and deploys the implant through the prostate. It is designed to increase prostatic urethral patency by providing prostate lobe tissue retraction while preserving the potential for future prostate procedures and is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men.

New Regulation Number: 21 CFR 876.5530

Classification: II

Product Code: PEW

Background

Device Name: UroLift System

Submission Number: K130651

Date of De Novo: March 7, 2013

Contact: NeoTract, Inc.,
Nancy Isaac, JD, MPH – VP, Clinical Affairs, Regulatory and Quality
4473 Willow Rd
Ste 100
Pleasanton, CA 94588

Requester's Recommended Classification: II

Indications for Use

The UroLift System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 50 and above.

Limitations

1. Caution: Federal Law restricts this device to sale by or on the order of a physician.
2. The UroLift® System should not be used if the patient has:
   - Prostate volume of >80 cc
   - An obstructive or protruding median lobe of the prostate
   - A urinary tract infection
   - Urethra conditions that may prevent insertion of delivery system into bladder
   - Urinary incontinence
   - Current gross hematuria
   - A known allergy to nickel
3. The safety of the delivery system has not been evaluated in the MR environment, and therefore, the delivery system should not be used within the MR environment.
4. The UroLift® Implant has been shown to be MR Conditional and can be scanned under the following conditions:
   - Static magnetic field strength of 3 Tesla or less
   - Maximum spatial gradient magnetic field of 720 Gauss/cm
   - A maximum whole-body-averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

Device Description

Device Name: UroLift® System

Device Model(s): UL400

The UroLift® System is composed of two main components: the UroLift® Delivery Device and UroLift® Implant (Figure 1). Each Delivery Device comes pre-loaded with one UroLift® Implant. The insertion of the UroLift® Delivery Device into the male urethra is performed under direct visualization using standard surgical technique, using a standard cystoscopy sheath and a Karl Storz 10324AA telescope. The UroLift® Delivery Device is designed to access the prostatic urethra and deliver one UroLift Implant through a lateral lobe of the prostate. The UroLift® Delivery Device is inserted into the urethra through the penile orifice and used to displace the urethra toward the prostatic capsule. A UroLift® Implant is then deployed transversely through the prostatic tissue. The Implants secure the retracted position of the urethra thereby maintaining an expanded urethral lumen, reducing fluid obstruction and improving lower urinary tract symptoms (LUTS). This is accomplished by holding the approximated position of the inner (urethral) tissue and the outer (capsular) tissue of the prostate with the UroLift® Implant (Figure 2).

De Novo Database

Device Classification under Section 513(a)(1)(de novo)

FDA Home › Medical Devices › Databases

1 to 10 of 117 Results
Decision Date To: *10/14/2014* **de novo**
Products: *Yes*

1 2 3 4 5 6 7 8 9 10 >

Results per Page 10

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Device Name	Requester	De Novo Number	510(K) Number	Decision Date
T2candida And T2dx Instrument	T2 Biosystems, Inc	DEN140019		09/22/2014
Nephrocheck Test System	Astute Medical, Inc	DEN130031		09/05/2014
Medtronic Duet External Drainage And Mon	Medtronic Neurosurgery	DEN120017		08/22/2014
Zinc Transporter 8 Antibody (Znt8ab) Eli	Kronus Market Development Associates, In	DEN140001		08/20/2014
Studio On The Cloud Data Management Soft	Dexcom, Inc.	DEN140016		08/19/2014
Rewalk	Argo Medical Technologies, Inc.	DEN130034	K131798	06/26/2014
Eeva 2.0	Auxogyn, Inc.	DEN120015	K120427	06/06/2014
Euroimmun Anti-pla2r Ifa	Euroimmun Us	DEN140002	K132379	05/29/2014
Quidel Molecular Direct Hsv 1 +2/Vzv Ass	Diagnostic Hybrids, Inc.	DEN140004	K133448	05/13/2014
Deka Arm System	Deka Integrated Solutions Corporation	DEN120016	K121215	05/09/2014

Reference

***De Novo* Database**

- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm

Submission Identification

DENXXZZZZ*

- DEN = *de novo*
- XX = year of submission (e.g., 14 = 2014)
- ZZZZ = submission increments from 0001

* Naming structure effective with new submissions as of Aug 2014.

Submission Identification

- **510(k)s that lead to de novos** - both 510(k) and DEN numbers
- **Direct *De Novos*** – no 510(k) number
- **DEN process began August 2014**
  - retroactively assigned DEN ID to prior *de novos*

Suggested Information for Inclusion in *De Novo* Application

Content Information - from 2014 Draft Guidance

Disclaimer:

- not for implementation (draft)
- however, may contain useful information to consider for inclusion in your submission

Suggested Information

1. Administrative Information:

- applicant name
- contact name
- address
- contact information (phone, fax, email)

Suggested Information

2. Regulatory History:

Prior submissions to FDA for same device

- prior 510(k)s and related NSE decisions
- IDEs
- Pre-Submissions (Pre-Subs)
- previously withdrawn/declined *de novos*

Suggested Information

3. Device Information and Summary

- device name
- device description
- intended use/indications for use statement
- technological characteristics
- labeling (directions for use)

Suggested Information

4. Classification Summary

- review of FDA classifications, regulations, and approved PMAs to confirm that your device has not already been classified
  - in other words, confirmation that this is a “new device”

5. Recommended Classification

- Class (i.e., either Class I or II)
- exempt or not-exempt
- justification for recommended classification, controls, and exemption (as applicable)

Suggested Information

6. Proposed Special Controls

- applicable to Class II devices ONLY

7. Supportive Evidence

- methods, data, results
- testing to include: pre-clinical, animal, clinical, where appropriate
- correlation between evidence and classification recommendation

Suggested Information

8. **Summary of Benefits**
9. **Summary of Known/Potential Risks to Health**
10. **Risk and Mitigation Information**
    - discussion of each risk, mitigation measure, and evidence
    - mitigation to include general and/or special controls

Suggested Information

11. Benefit-Risk Considerations

Discuss how benefits, with recommended general/special controls, outweigh risks

12. Device Labeling

per Section 201(m) of FD&C Act

Best Practices/Helpful Hints

Best Practices/Helpful Hints

1. **Do your homework and regulatory research to show your new device is eligible for *de novo*.**
   - Verify that your new product is not already classified
   - Research all available databases (510(k), PMA, classification) and prior decisions

   ➢ **Especially important if you pursue direct *de novo***

Best Practices/Helpful Hints

2. Be specific with and finalize the device description and intended use.

- The specifics of the device description and intended use will determine whether the new device has a predicate to which it may be compared.

Best Practices/Helpful Hints

3. Complete all required performance testing prior to submission of *de novo*.

- *De Novo a*pplication should be best effort to include all necessary information for FDA to make final de novo decision.
- Testing may include bench, animal, in vivo, in vitro, clinical.
- Each *de novo* will need the level of testing to characterize level of risk of device, demonstrate reasonable assurance of safety and effectiveness, and (as applicable), the appropriateness of special controls.
- Clinical testing not always be required, but likely in many cases.

Best Practices/Helpful Hints

4. Ensure that data support proposed intended use.

- If you propose intended use for multiple patient populations, provide evidence for all groups (or justification for not directly testing patient population)

Best Practices/Helpful Hints

5. Correlate each risk to health with a mitigation.

- Consider similarities of new device risk with mitigation used for similar devices
  - ✓ **Tip: Review special controls used for other granted de novo applications**
- Address each risk to health with at least one mitigation

Best Practices/Helpful Hints

6. Being Low Risk helps support de novo eligibility, but isn't sufficient to be granted a *de novo*.

A new device that is low risk may be eligible for a *de novo* **only**:

- if able to characterize risks to health **and**
- provide reproducible controls to manage those risks.

Does My Device Qualify for a *De Novo*?

1. Has the Device Type already been classified by FDA?

- **Device Type** includes both intended use and technological characteristics
- 510(k) Pathway: Is there an applicable predicate device?
- PMA Pathway: Has the device type been approved under PMA?

2. Factors to Consider for the New Device

- Does the device present low risk or moderate risk?
- Can we identify the risks to health associated with the new device?
- Can we identify the necessary controls (general and/or special) to mitigate the risks?

Conclusion

1. *De Novo* provides a means for a new medical device to get to market.

2. The eligibility for a *de novo* is based on several factors, such as FDA precedent, level of risk and the ability to characterize and mitigate risks of device.

3. The information needed in a *De Novo* includes evidence that demonstrates safety and effectiveness of new device and classification information.

4. Several key resources such as FDA Pre-Submissions and public domain information on web may be useful.

Providing Industry Education

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   - over 80 modules - videos, audio recordings, power point presentations, software-based "how to" modules
   - accessible on your portable devices http://www.fda.gov/Training/CDRHLearn
2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance
3. **Division of Industry and Consumer Education (DICE)**
   - If you have a question - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2014 or (301) 796-7100 (Live Agents 9am – 4:30 pm EST)

   Web Homepage:

   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm

Thank you