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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

WARNING LETTER

VIA FACSIMILE  
VIA FEDERAL EXPRESS

JUL 22 1999

Ashvin Desai  
President  
Ximed Medical Systems/Prosurg, Inc.  
ProSurg, Inc.  
2193 Trade Zone Boulevard  
San Jose, CA 95131

Dear Mr. Desai:

The Promotion and Advertising Policy Staff in the Office of Compliance of the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) has reviewed two of Prosurg Inc.'s (Prosurg's) Internet websites as well as press releases pertaining to uses associated with ProSurg's Transurethral Injection Needle System (TUNIS)<sup>TM</sup> and its Injection/Aspiration Needle Device. Both are devices within the meaning of section 201(h) of the Federal, Food, Drug and Cosmetic Act (the Act). We have determined that these devices are identical devices cleared with separate intended uses.

After a June 8, 1999 telephone conversation with you and careful review of the materials on your website, this office has determined that ProSurg created the trade names InjecTx<sup>TM</sup> and Bioject<sup>TM</sup> for the TUNIS<sup>TM</sup> device and the Injection/Aspiration Needle Device when they are used in combination with flexible and rigid endoscopes. Additionally, Prosurg created a website entitled [www.injectx.com](http://www.injectx.com) for the express purpose of promoting these combination devices for unapproved uses. Another indication of the relationship between ProSurg and the InjecTx site is that the Vice President of Marketing for ProSurg, Amy Neal, signed a "Dear Doctor" letter that appears on the InjecTx website.

ProSurg's TUNIS<sup>TM</sup> and the Injection/Aspiration Needle Device were cleared for marketing pursuant to FDA's premarket reviews of ProSurg's 510(k) submissions, k983765 and k983200, respectively, for the following intended uses:

K983765 indicates that the TUNIS<sup>TM</sup> device was cleared for use "independently or with commercially available rigid and flexible endoscopes, including laparoscopes, hysteroscopes, cystoscopes, resectoscopes, and suction/irrigation systems. These devices can be used for laparoscopic, hysteroscopic, cystoscopic, and other endoscopic and open surgical procedures designed for injection and

aspiration of fluids and solutions in the tissue or body. This device is not intended for injection of drugs.”

K983200 describes the intended use of the Injection/Aspiration Needle Device as follows: The device can be used “independently or with commercially available rigid and flexible endoscopes, including laparoscopes, hysteroscopes, cystoscopes, resectoscopes for transurethral injection/aspiration procedures. These devices can be used for laparoscopic, hysteroscopic, cystoscopic, and other endoscopic & open surgical procedures designed for interstitial injection/aspiration of biomaterials, fluids and solutions in the urinary bladder and lower urinary tract.”

The material on Prosurg’s InjecTx website makes extensive references to the use of the InjecTx device for injection to the prostate, for the treatment of benign and malignant prostate conditions, of drugs such as alcohol (ethanol) and antibiotics and injection of adenoviral vectors for gene therapy, and for delivery to body tissue of RF energy. Additionally the site promotes the device as the BioJect for the treatment, through the injection of drugs and bulking agents, of urinary incontinence. As described below, these statements have modified the products’ intended use, requiring the submission to FDA of a premarket approval application, and have resulted in the misbranding and adulteration of both the TUNIS device and the Injection/Aspiration Needle Device.

The InjecTx website at [www.injectx.com](http://www.injectx.com) makes numerous representations that the InjecTx device is effective in treating prostate conditions. The site contains a pictorial representation of the InjecTx device and a “Dear Doctor” letter, signed by Amy Neal, V.P. Marketing, that promotes the InjecTx device for the treatment of benign and malignant prostatic tissue through cystoscopic injection of alcohol (ethanol) or other sclerosing injectable agents. The letter further states that the safety and effectiveness of ethanol injection in prostatic tissue has been confirmed. The “Frequently Asked Questions” section of the website recommends that no other device be used for this procedure. It states “The InjecTx device has been designed for safe and effective transurethral injection, so as to create controlled and localized tissue necrosis deep within the prostatic tissue. Other injection devices or needle designs, which cannot duplicate these tissue effect [sic], may not produce safe and satisfactory clinical results.” The website also contains instructions for the injection procedure and a customer feedback form that encourages the use of injection therapy and feedback from practitioners who use the therapy. Although the site makes numerous references to clinical trials and includes summaries of studies, clinical evidence supporting the use of the InjecTx device for the treatment of benign and malignant prostatic tissue has not been received or cleared by the FDA.

The site also contains a page that says, “The transurethral injection therapy has compelling clinical advantages over drug therapy, conventional surgical intervention and other minimally invasive surgical alternatives, including Laser Systems, Radio-frequency, Microwave, Ultrasound and others. It also offers significant economic advantages to health care providers and insurance companies. . .” There have been no data submitted to FDA to support such claims. These claims imply that the procedure and the use of the device for the procedure have been compared with other treatment methods and may encourage patients and health care practitioners to make an uninformed choice of this procedure over other procedures or drug therapies.

The site also promotes the use of R.F. energy with the InjecTx device. A clinical case study entitled "Outpatient Tissue Ablation Using Transurethral Absolute Ethanol Injection In The Treatment of Benign Prostatic Hyperplasia," found at [www.injectx.com/clinical\\_case\\_studies.html](http://www.injectx.com/clinical_case_studies.html) states "The use of the InjecTx – Transurethral Injection device (InjecTx.), which employs a hollow core needle, has been given 510(k) approval by the Food and Drug Administration (FDA) for RF energy tissue ablation."

The 510(k) record for K983765 states that ProSurg was explicitly advised that the device was not designed for delivery of R.F. energy to body tissue. CDRH's Office of Device Evaluation requested that ProSurg provide a statement regarding the use with or connection of the device to an R.F. energy source. You responded to this request in a December 7, 1998, facsimile. In that facsimile, ProSurg revised its intended use and instructions to state that "the Injection/Aspiration Needle Probes/Devices do not have any plugs or adapters for connection to a R.F. energy source. The proposed device is not designed for delivery of R.F. energy to body tissue."

The website also contains a link to an article entitled "Delivery of Adenoviral Vectors to the Prostate for Gene Therapy." The article includes a statement that the delivery of adenoviral vectors directly to the prostate provided the "best route to treat local regional prostate cancer by viral-based gene therapy." Although there is no explicit reference to the InjecTx device, the implication created by the link to the article and a picture of the InjecTx device after the article is that the InjecTx device can be utilized to deliver adenoviral vectors to the prostate in the treatment of cancer. The 510(k) record clearly states that ProSurg should not market its device for a specific intended use, i.e. the treatment of benign or malignant prostate conditions. However, references to specific uses for the InjecTx device are found throughout the InjecTx website. Another instance of this can be found in the "Dear Doctor" letter noted earlier, which promotes using the device and procedure to "cause selective cell necrosis in benign or malignant prostatic tissue."

There is also a link on InjecTx's website entitled "Gene Therapy." The "Gene Therapy" page contains the phrase "What's Next!" and several links referring to aspects of gene therapy. There is also a picture of the InjecTx device with a caption that reads, "Gene Therapy Delivery Systems." The content of this page further implies that the InjecTx device can be used in gene therapy, a component of some cancer treatments.

Additionally, ProSurg, through its InjecTx website, is promoting the use of the Bioject™ device for the unapproved use of injection of anesthetic agents and bulking agents to treat incontinence.

FDA's regulations at 21 CFR 801.4 provide that the "intended use" of a device refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.

The device is therefore, misbranded and adulterated within the meanings of sections 502(o) and 501(f)(1)(B), respectively, of the Act. It is misbranded because ProSurg did not submit to FDA a notice or other information respecting the device as required by section 510(k) of the Act. The company did not submit data to support the

claims made in the press release or in other materials on the InjecTx website. The device is adulterated because it is a class III device without either an approved PMA in effect as required by section 515 of the Act or an approved investigational device exemption as required by section 520(g) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies associated with ProSurg's InjecTx device. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may also be reflected in other promotion and advertising materials used by your company. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in FDA's initiating regulatory action without further notice. These actions include, but are not limited to, seizure, injunction and/or civil money penalties.

Please notify this office in writing, within 15 working days of your receipt of this letter, of the specific steps that you have taken to correct the noted violations. Your response should include steps being taken to address any misleading information currently in the market place and to prevent similar violations in the future. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Direct your response to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff (HFZ- 302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, San Francisco District Office, Food and Drug Administration (HFR-PA140) 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,



Lillian Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health