

K092090
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Byrne Medical Incorporated
Traditional 510(k): ERBELIFT™ Hand Pump and Flexible Probe

510(k) SUMMARY

Submitted By: Byrne Medical Incorporated
3150 Pollock Drive
Conroe, TX 77303
Tel: 936-539-0391
Fax: 936-539-2381

NOV 30 2009

Contact Person: Chris Hierholzer
Quality Control Manager

Date Prepared: April 22, 2009

Common Name: Injector

Trade/Proprietary Name: ERBELIFT™ Hand Pump and Flexible Probe

Classification Name: Endoscopic Injection Needle (21 CFR Part 876.1500)

Product Code: FBK

Legally Marketed

Predicate Device: Endoscopic Injection Needle 510(k) Number: K924102
and Endoscopic Injection Needle/Snare 510(k) Number:
K040961

Device Description:

The ERBELIFT™ Hand Pump and Flexible Probe are used for the delivery of pressurized sterile normal saline to the submucosa to lift polyps or other mucosal lesions. A control syringe is filled with sterile normal saline. The filled syringe is attached to the Flexible Probe via a hub with a standard luer lock and loaded into the Hand Pump. The Flexible Probe is primed with the saline and then the distal end of the Probe is placed down the working channel of the endoscope. Under direct visualization, the Probe's tip is placed against the target tissue without puncturing the mucosa. Then, the trigger of the Hand Pump is squeezed to produce pressurized saline from the control syringe and through the Probe into the bed of the polyp or lesion to achieve a desired tissue lift.

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The Hand Pump is made of nylon and stainless steel. It is 8-3/4" (22 cm) long, 6" (15 cm) wide, and having a thickness of 2-1/2" (6 cm). The Pump per squeeze of the handle delivers approximately 0.75 ml of normal saline. The Flexible Probe is made of Polyetheretherketone (PEEK) and nylon (Note: Medical grade inks and reducer are used to imprint logos on the device.). It has a 1.3 mm Outer Diameter and length of 260 cm. The distal tip is tapered to approximately 0.005" and delivers a jet stream of 120 um. The Hand Pump with the Flexible Probe can generate pressures in the approximate range of 145 to 650 psi which correlates to flow rates of 17 to 38 ml/minute.

The Hand Pump is reusable with the Flexible Probe being provided as sterile and single use.

Intended Use:

The ERBELIFT™ Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Similarities and Differences of the Proposed Device to the Current Devices (Predicate Comparison/Substantial Equivalence):

Similarities

The ERBELIFT Hand Pump and Flexible Probe have an intended use that is within the intended uses of the predicates. Also, like the predicates, the purpose is the same in that the devices are for the injection of fluids into tissue for endoscopic purposes. The lifting medium (i.e. sterile normal saline) is also a part of the types of solutions identified for use with the predicates. The materials used for the proposed device are also similar to the predicates. Additionally for accompanying various types and sizes of endoscopes, the working length of the Flexible Probe is comparable (260 cm) to the predicates (230 cm). Both predicates also require the need for a syringe connected via standard luer lock like the proposed device (Note: A designated control syringe is used to ensure sufficiency in regards to strength and durability. The control syringe is identified in the Instructions For Use for the proposed device.). Furthermore, the Flexible Probe is sterilized via Ethylene Oxide, single use, and disposable as are the predicates.

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Differences

The Hand Pump is an additional component for the ERBELIFT™ system as compared to the predicates. The Pump provides the force to the control syringe to induce the pressurized fluid into the submucosa as compared to the force of the needle and fluid hand pushed from a syringe to lift polyps or other mucosal lesions.

The technology employed in the ERBELIFT product has been widely used in medical devices since the 1900s. Needle-free injection devices, first called "jet injectors," were developed in the 1930s and used extensively for over 50 years in mass human vaccination programs for smallpox, polio, and measles.^{1,2,3} Using mechanical compression to force fluid through a small orifice, these devices produced a high-pressure stream 76 to 360 μm in diameter (compared to 810 μm for a 21-gauge needle) that could penetrate skin and subcutaneous tissue⁴. These devices are used today to inject insulin, cardiovascular dyes, etc. The manual fluid injectors are classified by FDA as product code KZE.

Functional bench and animal lab testing has demonstrated that the ERBELIFT Hand Pump and Flexible Probe lifts the submucosa safely and effectively. See Section III, Product Data - Performance Testing.

The types of materials used for the Flexible Probe are similar to the predicates but specific materials are slightly different. Therefore, biocompatibility of the specific materials for the Probe was demonstrated. See Section III, Product Data - Biocompatibility Study.

Besides the use of a Hand Pump with the ERBELIFT system to provide the force needed to lift the mucosa in comparison to force of a needle and fluid pressure from the predicates, the working diameter and tip/fluid stream of the ERBELIFT Flexible Probe is much smaller (i.e. a working diameter of 1.3 mm with a tipped Inner Diameter of approximately 0.120 mm as compared to a working diameter of 2.5/3.0 mm respectively with a 25 G needle/tip of 0.508 mm Outer Diameter and 0.241 mm Inner Diameter for the predicates). For the ERBELIFT Flexible Probe the smaller diameter and fluid stream with no mechanical needle injection causes less penetration tissue damage. Also, because fluid seeks the path of least resistance it is easier to find the tissue plane and easier to create a lift. See Section III, Product Data - Performance Testing.

Conclusion:

The ERBELIFT Hand Pump and Flexible Probe's intended use is a part of the predicate's indications in the previously cleared 510(k)s. The ERBELIFT system has slightly different principles of operation and technological characteristics as the predicate devices. The use of an amplified fluid force via the Hand Pump as compared to the force of a needle and pressure from pushing a syringe by hand with the predicates (i.e. mechanical trauma of a needle with less fluid pressure) was found to be less traumatic to tissue because of the penetration size being much smaller as well as it being easier to do because of fluid dynamics. The modifications of having a Hand Pump instead of a needle as well as a Flexible Probe with a smaller working diameter and tip configuration did not raise any new safety or efficacy concerns. In conclusion, all the changes were verified or validated. As a result, the ERBELIFT Hand Pump and Flexible Probe did not adversely affect safety or effectiveness.

¹ Reis EC, Jacobson RM, Tarbell S, Weniger BG. Taking the sting out of shots: control of vaccination-associated pain and adverse reactions. *Pediatr Ann.* 1998;27:375-386.

² Hingson RA, Davis HS, Rosen M. The historical development of jet injection and envisioned uses in mass immunization and mass therapy based upon two decades experience. *Mil Med.* 1963;128:516-524.

³ Chase CCL, Daniels CS, Garcia R, et al. Needle-free injection technology in swine: Progress toward vaccine efficacy and pork quality. *J Swine Health Prod.* 2008;16(5):254-261. (<http://www.aasv.org/shap/issues/v16n5/v16n5p254.htm>)

⁴ Mitragotri S. Immunization without needles. *Nat Rev Immunol.* 2005;5:905-916



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Byrne Medical, Inc.
% Mr. Daniel W. Lehtonen
Sr. Staff Engineer – Medical Devices
Intertek Testing Services
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

NOV 30 2009

Re: K092090
Trade/Device Name: Erbelift Hand Pump and Flexible Probe
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: September 28, 2009
Received: September 29, 2009

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

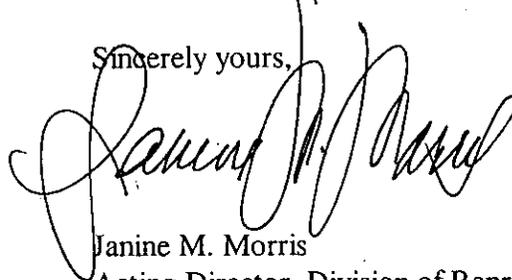
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092090

Device Name: Byrne Medical, Inc.'s ERBELIFT™ Hand Pump and Flexible Probe

Indications For Use:

The ERBELIFT Hand Pump in conjunction with an ERBELIFT Flexible Probe is indicated for the induction of sterile normal saline into the submucosa to lift polyps or other mucosal lesions using direct visualization through a flexible endoscope.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092090