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CONFIDENTIAL

510(k) Summary of Safety and Effectiveness
ByPass LTD, CorLink™ Automated Anastomotic System
510(k) Number K033979

This 510(k) notification is submitted by ByPass LTD.3 Hasadnaot St.Herzelia B 46728 Israel
The contact person is Amir Loshakove, General Manager.

This 510(k) notification describes the CorLink™ Automated Anastomotic Device indicated for creation of an anastomosis between a venous graft conduit and the aorta for coronary artery bypass grafting. The Coring punch device is intended for creating the aortotomy in which the implanted device will be deployed.

The Coring punch device is equivalent to the punch already cleared as a component of the *CorLink™ AAS* (K020470) with respect to intended use. The major differences between the two systems are:

1. The Piercing Tip and the Tissue Grabber are in one piece in the modified coring punch
2. Tissue Grabber button was replaced by an automatic Tissue Grabber activation button component
3. The Tissue Grabber in the modified coring punch contains 3 barbs instead of 2 as in the 510k cleared coring punch design
4. The Cylinder Cutting Edge diameter will range from 2.5 mm to 3.6 mm and from 2.9 mm to 4.0 mm in the 2.0 mm and 4.0 mm size kits (in 0.1 mm increments each), respectively.
5. The modified coring punch is single use only, whereas the 510(k) cleared coring punch was for single patient use.

The improvement in the punch mechanism does not require any design, structural, or dimensional changes to the Handle, the Inserter, Sizer and the Implant.

Information on risk analysis of the modifications and performance testing provided in the application demonstrates equivalence to the predicate device with respect to performance.

Based on the performance data gathered, the device modifications do not raise any new questions of safety or effectiveness.

Based on the information provided the modification of the *CorLink™ AAS* to include the Coring punch is substantially equivalent to the cleared *CorLink™ AAS* using the punch with respect to intended use, technological characteristics, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2004

By-Pass Makafim Ltd.
c/o Mr. Jonathan S. Kahan
Hogan and Hartson
555 13th Street NW
Washington, DC 20004-1109

Re: K033979
CorLink™ Automated Anastomotic System – Coring punch modification
Regulation Number: 21 CFR 870.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II (two)
Product Code: FZP
Dated: December 22, 2003
Received: December 23, 2003

Dear Mr. Kahan:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE ENCLOSURE

510(k) Number (if known): K033979

Device Name: CorLink™ Automated Anastomotic System – Coring punch modification

Indications for Use: The CorLink AAS is indicated for creation of an anastomosis between a venous graft conduit and the aorta for coronary artery bypass grafting (CABG). The Coring punch component penetrates the aorta and cuts a circumferential aortotomy in which the implanted device will be deployed.

Prescription Use ___✓___ OR Over the Counter Use_____
(Per 21 CFR 801.109)

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

Diana R. Vo-Nhu

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of General and Restorative Devices

510(k) Number K033979