MAR 8 2002

510(k) Summary of Safety and Effectiveness
ByPass LTD, CorLink™ Automated Anastomotic System
510(k) Number K020470

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 a device intended for use in Coronary Artery Bypass Grafting procedures for creating a rapid sutureless proximal anastomosis between a grafted vessel and the aorta. The C-Punch device is intended for creating the aortotomy in which the implanted device will be deployed.

The C-Punch device is equivalent to the Linear Punch already cleared as a component of the CorLink AAD (K011589) with respect to intended use, materials and performance of the aortotomy. The major difference between the two systems is the method by which the punch creates the aortotomy. The Linear Punch creates an aortotomy by insertion of the punch tip to the aortic wall and retraction of the punch tip against the cutting tube. The cut piece of the aortic wall is contained within the cutting tube. The C-Punch achieves the same aortotomy sizes and quality by insertion of a central needle and cutting/coring the tissue by rotating the punch device clockwise and counterclockwise. The cut piece of the aortic wall is contained within the cutting/coring tube.

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™ AAD to include the C-Punch is substantially equivalent to the cleared CorLink™ AAD using the Linear 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 8 2002

ByPass, Ltd.
c/o Jonathan Kahan
Hogan and Hartson
555 Thirteenth Street, N.W.
Washington, D.C. 20004 -1109

Re: K020470
Trade Name: CorLink™ AAD
Regulation Number: 878.4300; 878.4300
Regulation Name: Implantable Clip; Aortic Stapling Device
Regulatory Class: II
Product Code: FZP, NCA
Dated: February 19, 2002
Received: February 20, 2002

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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). 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE ENCLOSURE

510(k) Number (if known): K020470

Device Name: CorLink™ Automated Anastomotic Device

Indications for Use: The ByPass CorLink™ Aortic Anastomotic Device (CorLink™ AAD) is intended to be used in CABG procedures for creating a sutureless proximal anastomosis between the Aorta and a venous graft conduit.

(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 General and Restorative Devices

510(k) Number K020470

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

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020470