DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2003

ByPass Maakafim, Ltd.
c/o Mr. Jonathan Kahan
Hogan and Hartson
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K011589
Trade/Device Name: CorLink™ AAD
Regulation Number: 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NCA
Dated: November 8, 2001
Received: November 8, 2001

Dear Mr. Kahan:

This letter corrects our substantially equivalent letter of December 26, 2001 regarding the CorLink™ AAD. We have corrected the product code from FZP to NCA.

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 (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); 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 continue 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 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Miriam C. Provost

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

510(k) Number (if known): K011589

Device Name: *ByPass CorLink™ Automated Anastomotic Device* (CorLink™ AAD), consisting of the *Implant, Inserter, Punch, Handle, Sizers and everting tool.*

Indications for Use: The *ByPass* CorLink™ Anastomotic Device is intended to create vascular anastomoses between blood vessels. Specifically, the device is indicated for creation of a sutureless proximal anastomosis between a venous graft conduit and the aorta for coronary artery bypass grafting (CABG) procedures.

(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, Ear, Nose and Throat, and Radiological Devices

510(k) Number K011589

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

NRO for CMW
(Division Sign-Off)
Division of Gene... Restorative and Neurological Devices

510(k) Number K011589

K011589

DEC 2 6 2001

510(k) Summary for the
ByPass CorLink™ AAD
510(k) Number K011589

Submitter's Name:

Amir Loshakove, Ph.D.
ByPass Ltd.
3 Hasadnaot Street
Herzelia
Israel
Telephone: 972-9-9704321 / Fax: 972-9-9704355

Device:

Trade name: ByPass CorLink™ AAD
Classification Name: Implantable Clip
Product Code: FZP

Predicate Devices:

The *ByPass* CorLink™ AAD is substantially equivalent to the USSC One-Shot Sutureless System (K970793), the USSC Auto Suture Vascular Anastomosis Clip (K933887) and the Deknatel Gwathmey Vascular Stapling Kit (K864146).

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Device Description:

The *ByPass* CorLink™ Automated Anastomotic Device (CorLink™AAD) intended use is to create the proximal graft-aorta anastomosis during a CABG procedure.

The CorLink™ AAD, delivered with an introducer kit, is a single use system. The implant is made of self-expanding nitinol and composed of two main elements: the self-expandable center area and the flexible pins at both ends.

The center is made of connected elliptic arches, which upon implant expansion exert a radial force on the everted vein end and the aortic wall. The flexible pins from both ends of the device fold and "bite" the aortic wall in a way that connects

and compresses the grafted vessel against the aorta. This procedure stabilizes the implant at the desired location and creates a sealing surface around the anastomosis.

Technological Characteristics and Performance:

All materials used in the *ByPass* CorLink™ AAD are either commonly used in medical applications or have been proven to be biocompatible through biocompatibility testing. Bench and animal testing has demonstrated that the CorLink™ AAD is safe and effective and that its performance is substantially equivalent to its predicate devices.