First Call, Inc.
660 E 200 N, Warsaw, IN 46580

JAN 17 2006

K 052642

510(k) Summary of Safety and Effectiveness

SUMMARY PREPARED:	December 28, 2005
510(k) SPONSOR/APPLICANT:	First Call, Inc. 660 E 200 N, Warsaw IN 46580
510(k) PREPARER and CONTACT PERSON:	Dina L. Weissman, J.D. P.O. Box 205, Derby CT 06418 Telephone: (203) 287-0485 Email: DLWeissman@aol.com
TRADE NAME:	Suturing Washer
COMMON NAME:	Marker, Cardiopulmonary Bypass (Vein Marker)
CLASSIFICATION:	unclassified
DEVICE PRODUCT CODE:	MAB
PREDICATE DEVICE:	Cook® Vein Graft Ring Marker, K864101, Cleared 30 October 1986
DEVICE DESCRIPTION:	This 4.5mm outer diameter suturing washer is manufactured from either stainless steel (ASTM F-138) or titanium (ASTM F-136). It is permanently implanted and must be sterilized prior to use.
INTENDED USE:	This single use device is for radiological identification of the aortic anastomosis in coronary artery bypass surgery
COMPARISON TO PREDICATES:	The First Call, Inc. Suturing Washer is similar to the listed predicate device in intended use, performance characteristics, materials of construction, manufacturing methods and design.

PREMARKET NOTIFICATION

I. DEVICE SPECIFICATIONS

TRADE NAME: Suturing Washer

COMMON NAME: Marker, Cardiopulmonary Bypass (Vein Marker)

CLASSIFICATION: Unclassified

DEVICE PRODUCT CODE: MAB

Narrative Description

The suturing washer is manufactured from stainless steel, conforming to ASTM F-138, or titanium, conforming to ASTM F-136.

This device is for single use and must be sterilized prior to use.

Intended Use/Indications for Use

This single use device is for radiological identification of the aortic anastomosis in coronary artery bypass surgery

Physical Description

The suturing washer is made from a solid piece of stainless steel (conforming to ASTM F-138) or titanium (conforming to ASTM F-136). The circular device has an outer diameter of 4.5mm and an inner diameter of 1.5mm. It is approximately 1mm in thickness.

The part number is provided in **Exhibit A**.

The engineering drawing is supplied in **Exhibit B**.

Labeling

A proposed label and draft instructions for use are included in **Exhibit C**.

Predicate Device

There is no clearance letter or 510(k) summary available online for the predicate device, but the printout from the FDA 510(k) premarket notification database and the page from the Cook® website are attached in **Exhibit D** as evidence of the predicate being legally marketed. The predicate is

- Cook® Vein Graft Ring Marker, K864101, cleared 30 October 1986

A discussion of the similarities to and difference from these devices is in the Substantial Equivalence section, following the Manufacturing section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2006

First Call, Inc.
c/o Ms. Rebecca Kitchens
President
660 E 200 N
Warsaw, IN 46580

Re: K052642
Trade Name: Suturing Washer
Regulation Name: Suturing Washer
Regulatory Class: Unclassified
Product Code: MAB
Dated: December 28, 2005
Received: December 30, 2005

Dear Ms. Kitchens:

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 (240) 276-0120. 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 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/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K052642

Device Name: Suturing Washer

Indications for Use:

This single use device is for radiological identification of the aortic anastomosis in coronary artery bypass surgery.

Prescription Use XXXXX **(Part 21 CFR 801 Subpart D)**	AND/OR	Over-The-Counter Use _____ **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vedder

)ivision Sign-Off)
ivision of Cardiovascular Devices

10(k) Number K052642