Maternus, Inc. ~ 13223 Hunters Lark ~ San Antonio, TX 78230 ~ 210.479.4001 ~ 210.479.4000 fax CONFIDENTIAL

MAY - 3 2001

510(k) SUMMARY

Substantial Equivalence & Safety & Effectiveness Information

[March 6, 2001]

I. **Proprietary Name:** **Koala Clamp**

II. **Common Name:** Umbilical Cord Clamp Device

III. **Classification Name:** Umbilical Clamp (HFW)

IV. **Substantial Equivalence:** The Koala Clamp is substantially equivalent to the Hospital's Clamp by DirectMed, Inc., a legally marketed device in the US. [510(k) no. 974227]

V. **Description of Device:** The Koala Clamp is a disposable, single-use obstetric device that is intended for use to clamp the umbilical cord following birth. The Koala Clamp is formed from injection-molded plastic. *See Material Specifications for plastic specifications and biocompatibility information.* The Koala Clamp measures approximately 44mm x 24mm x 7mm when closed and weighs approximately 0.09 ounces. (This weight is comparable with the weight of the predicate Hospital's clamp.) The plastic is preferably transparent (clear plastic). The Koala Clamp has no accessories.

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VI. Statement of Intended Use: The sole indication for use of the Koala Clamp is to clamp the umbilical cord following birth

VII. Comparison of Present Device & Predicate Device:

Comparison Chart of Koala Clamp and Predicate Device		
	Koala Clamp	***Hospital's Clamp***
Indications for Use	The sole indication for use of the Koala Clamp is to clamp the umbilical cord following birth.	To be used for obstetrics only. Umbilical cord clamp with side fasteners to prevent the umbilical cord from going out of the blocking combs. Irreversible closure to prevent accidental opening.
Target Population	All births	All births
Materials: Plastic	Lexan 144R (alternate: Lexan 124R)	Unknown
Biocompatible	Yes	Yes
Dimensions: Infant Clamp	43.5mm x 23.9mm x 6.5mm	55mm x 11mm x 10mm
Weight of Total Unit	0.086 oz	0.10 oz
Sterility	Ethylene Oxide Gas(alternate: Gamma-sterilized)	Ethylene Oxide Gas
Anatomical Sites	Umbilical Cord	Umbilical Cord

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2001

Mr. Ronald B. Hicks
Vice President and COO
Maternus, Inc.
13223 Hunters Lark
SAN ANTONIO TX 78230

Re: K010695
Koala Clamp
Dated: March 6, 2001
Received: March 8, 2001
Regulatory Class: II
21 CFR §884.4530/Procode: 85 HFW

Dear Mr. Hicks:

We have reviewed your Section 510(k) 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 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K010695

Device Name: Koala Clamp

Indications for Use: The sole indication for use of the Koala Clamp is to clamp the umbilical cord following birth.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010695

Prescription Use ✓
(Per 21 CFR 801.109)