JUL 14 1999 K991338

IRVINE SCIENTIFIC™

## 510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

**Submitted by:** Irvine Scientific Sales Co., Inc.
2511 Daimler Street
Santa Ana, CA 92705-5588

Telephone: (800) 437-5706
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Contact: Roberta L. Johnson

Date Submitted: April 16, 1999

**Device Identification:**

| | |
|---|---|
| Trade Name: | Bovine Serum Albumin (BSA) |
| Common Name: | Protein supplement for in vitro embryo culture |
| Classification Name: | Reproductive Media (21 CFR, 886.6180) |

**Predicate Device:**

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335

**Description:**

Bovine Serum Albumin, Fraction V 10% solution consists of Bovine Serum Albumin from United States source animals (10mg/mL) in a sterile saline solution. Bovine Serum Albumin, Fraction V Powder consists of BSA from United States source animals.



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**Intended Use:**

Bovine Serum Albumin is intended for use in assisted reproductive procedures that require protein supplementation. These procedures include in vitro fertilization, embryo culture and growth.

**Technological Characteristics:**

Depending upon the procedure used, an appropriate amount of pre-warmed, equilibrated BSA is withdrawn, and added to the culture dish and support medium. After the desired stage of embryo development is achieved, the embryo is removed from the culture dish, placed into a HEPES-buffered transfer medium, and implanted into the patient. BSA is not intended to contact the patient.

**Performance Data:**

BSA is assayed by mouse embryo assay prior to release to market. This assay assures that the product is both functional for its intended use, the support of embryonic growth, and that no toxic components are present in the formulation. Bovine Serum Albumin has been used in a variety of clinical settings, for their intended use, for a number of years. In that time, the product has become one of the standard protein supplements used for the in vitro fertilization and growth of human gametes and embryos.

**Additional Information:**

Mouse embryo testing will be performed as a condition of release for this product, as well as endotoxin and sterility testing. Results of all release assays performed will be reported on a lot-specific certificate of analysis, and will be indicated on the labeling.

**Conclusion:**

The conclusion from performance testing, as well as a review of the historical information contained in professional literature shows that Bovine Serum Albumin is suitable for its intended use, and meet the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1999

Ms. Roberta L. Johnson
Manager, Regulatory Affairs
Irvine Scientific, Inc.
2511 Daimler Road
Santa Ana, CA 92705-5588

Re: K991338
Bovine Serum Albumin (BSA)
Dated: April 16, 1999
Received: April 19, 1999
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Ms. Johnson:

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) 594-4613. 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"(21 CFR 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,

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

Enclosure

## INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K991338

Device Name: Bovine Serum Albumin (BSA)

Indications for Use:

Bovine Serum Albumin ((BSA) is intended for those assisted reproductive procedures that require the use of a protein supplement. In particular, BSA is intended for use during in vitro fertilization, during in vitro embryo culture to the desired stage of embryo development, and for the cryopreservation of human embryos.

(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, ENT,
and Radiological Devices
510(k) Number K991338

Prescription Use ✓
(Per 21 CFR 801.109)