

Drager Inc.

K961687

Dec. 13, 1996

2. SUMMARY AND CERIFICATION

2.1 Identification

Applicants Name and Address: **Drager Inc.**
Critical Care Systems
4101-100 Pleasant Valley Rd.
Chantilly, Virginia 22021
phone: (703) 817 0100
fax: (703) 817 0101

Contact Person: **Harald Kneuer**
Regulatory Affairs Manager
phone: (703) 817 0100
fax: (703) 817 0101

Manufacturers Address: **Dragerwerk AG**
Moislinger Allee 53-55
23542 Luebeck
Germany

Date of Application: April 24, 1996

Device Name: **Evita 4**

Registration Number: Owner/Operator ID No. Drager Inc.: 24 31 188
Registration No. Dragerwerk AG: 96 11 500

Classification:

~~Classification:~~ Class II JM
Panel: 73
Code: CBK
Classification Name: Ventilator, Continuous
Device Listing #: A911151

Predicate Device(s):

Drager Evita 1, 510(k) Number: K92 49 30
Drager Capnosat, 510(k) Number: K92 28 49
Siemens Servo 300; 510(k) Number: K90 28 59