**Hysteroscopic And Laparoscopic Insufflators: Submission Guidance For A 510(K) (Text Only)**

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This guidance was written prior to the February 27, 1997 implementation of FDA’s Good Guidance Practices, GGP’s. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP’s.

DRAFT: August 1, 1995

(Replaces portions of previous :"Hysteroscopes & Laparoscopes,

Insufflators & Other Related Instrumentation: Submission

Requirements for a 510(k)", dated March 25, 1994)

Prepared by: Obstetrics-Gynecology Devices Branch

Office of Device Evaluation

Center for Devices and Radiological Health (FDA)

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Introduction

This document outlines the information to be submitted in a 510(k)

premarket notification for hysteroscopic and laparoscopic insufflators.

For devices that differ significantly from those already on the market,

FDA may require additional information specific to those differences.

This guidance represents a greatly expanded version of our previous

guidance on insufflators, which was included in the March 25, 1994,

"Hysteroscopes & Laparoscopes, Insufflators & Other Related

Instrumentation: Submission Requirements for a 510(k)".

I. Device Name

Provide both the trade or proprietary name of the instrument, as

well as the common or usual name for the particular type, and specify (i)

hysteroscopic or laparoscopic and (ii) gas or liquid.

II. Predicate Device Name

Identify the legally marketed device(s) to which the new device will

be compared. Be as specific as possible, e.g., proprietary and common

name, manufacturer, model number, 510(k) reference number, pre-Amendments

status, etc. The 510(k) should include a tabbed section with product

literature (description, specifications, labels & labeling, etc.) on the

predicate device.

III. Administrative Information

Establishment Registration #

Contact Person and Title

Telephone number and FAX number

IV. Classification: Class II (Special Controls)

Give the CFR classification regulation number for the device, as

well as its classification:

Device Class CFR Reference

Hysteroscopic

Insufflator II 21 CFR 884.1700

Laparoscopic

Insufflator II 21 CFR 884.1730

V. 514 Performance Standards: None Applicable

Performance standards under 514 of the Act have not been developed

for these devices. Reference is made in later sections of this guide to

voluntary industry standards.

Laparoscopic Insufflators

I. Intended Use

Identify the intended use of the device, being as specific as

possible. For example:

This device is intended to facilitate the use of the

laparoscope by filling the peritoneal cavity with gas to distend it (21

CFR 884.1730).

II. Description of Insufflator

A. Physical and/or Electronic Description

1. Provide a diagram illustrating the flow of gas from its

source to the exit port of the scope. Include all safety features,

filters., and any special features, such as a gas warmer.

2. Indicate whether the device regulates and/or displays each

of the following parameters:

Displays Regulates

Intra-abdominal Pressure

Flow Rate

Volume Delivered

3. Distension Media

a. What is the gaseous distension medium?

b. What is the source of the medium?

c. If the device can be used with either CO2 or N2O,

describe the necessary calibration procedures and the connector indexing

system.

4. Filter (If applicable)

Use of a hydrophobic filter between the patient and the

insufflator to prevent patient cross-contamination is highly recommended.

The following specifications for the filter should be provided:

a. pore size (0.2 micron or less)

b. type

c. materials, including casing and filter material

d. location

5. Tubing (If applicable)

The following specifications for the tubing should be

provided: dimensions and materials for tubing and connectors. Generally

accepted materials for the tubing include silicone or PVC (most common).

Note: If the insufflator is intended for both hysteroscopic and

laparoscopic insufflation ( or hysteroscopic insufflation and

laparoscopic irrigation), you should provide the following information:

A detailed discussion of the redundant fail-safe mechanisms that

your device employs to insure that the device is not inadvertently used

for the incorrect procedure. Inadequate fail-safe mechanisms will result

in product clearance delays.

B. Full Listing of Performance Specifications

1. Indicate the maximum and default values for each of the

following parameters.

Default Maximum\*

Pressure (mmHg)

Flow rate (cc/min)

FDA has currently cleared for marketing laparoscopic

insufflators with maximum flow rates up to 20 l/min. The maximum

sustained intra-abdominal pressure should not exceed 30 mmHg.

Submissions for devices with maximum flow rates/pressures above these

levels must include test data demonstrating that the higher flow

rates/pressures do not adversely affect safety and effectiveness.

2. Description of key safety features. Indicate which features

are implemented by hardware and which are implemented by software. Some

recommended features are:

a. Overpressure protection

(1) Pressure overshoot not to exceed 45 mmHg for more

than 15 seconds when establishing pneumoperitoneum.

(2) Pressure relief at max pressure or when patient

pressure exceeds set pressure by more than 5 mmHg for more than 5 sec.

(3) Continuous, non-defeatable audible alarm and visual

indicator at maximum pressure. 5 second delay allowed; temporary

disabling not to exceed 30 seconds

b. Supply tank

(1) The supply tank connection should be pin-indexed to

guard against inadvertent use of N2O, regardless of whether the device

allows use of this media.

(2) Front panel should display the amount of gas

remaining in the supply tank, and a visual/audible alarm should warn the

user when the level falls below some reasonable value.

c. Monitoring of the volume of gas delivered is desirable.

C. System Level Hazard Analysis

The system level hazard analysis should identify each potential

patient hazard, the cause of the hazard, the level of concern, and the

steps taken to address the potential hazard. Common hazards include:

over-pressurization, gas intravasation, electric shock, and

electromagnetic compatibility.

D. Software

Insufflators that are software-controlled may be either minor or

moderate concern devices, depending on the design of the particular

device. The guidance document "Reviewer Guidance for Computer

Controlled Medical Devices" discusses ODE's general requirements for

software documentation. You should pay particular attention to the

following elements:

1. Structure chart or flow chart describing software

architecture

2. Summary of software development procedures, including change

procedures

3. Software Requirements Specification (ref IEEE/ANSI 830-1984),

with traceability back to the Hazard Analysis

4. Verification and Validation Test plan, including Pass/Fail

criteria and traceability back to the requirements

5. System level test results

6. Signed certification that "Software development was followed,

that good quality assurance procedures were adhered to, and that test

results demonstrate that the system specifications and the functional

requirements were met".

7. Software version number and date

E. Electrical safety

The submitter should provide either:

Certification that the device complies with

applicable electrical safety standards (e.g., IEC 601-1, UL 544, UL

2601); or

Test results which guarantee a similar level of

protection.

F. Electromagnetic compatibility

The submitter should provide either:

Certification that the device complies with

applicable standards for Immunity and Emissions (such as CISPR 11, IEC

601-1-2); or

Test results which guarantee a similar level of

protection; or

Justification for why this information is unnecessary

(e.g., due to device design or working conditions).

III. Comparison Table

Provide a table that lists the similarities and differences between

your device and the predicate devices(s). The table should include:

intended use, design features, maximum flow rate, maximum output

pressure, important safety features, and any other relevant device

characteristics.

IV. Labeling

Indications for Use

This device provides CO2 gas distension of the abdomen for diagnostic

and/or operative laparoscopy. See the operators manual of your

laparoscope for specific indications for use.

Contraindications for Use

Use of this device for intraabdominal distension is

contraindicated whenever laparoscopy is contraindicated. See the

operators manual of your laparoscope for absolute and relative

contraindications.

This device is contraindicated for hysteroscopic insufflation - it

must not be used for intrauterine distension.

Note: The distension pressure of a laparoscopic

insufflator should not exceed 30 mmHg.

Warnings

Metabolic Acidosis and Resultant Cardiac Irregularity.

Prolonged intra-abdominal pressures greater than 20 mmHg should be

avoided. This can cause any of the following:

Decreased respiration with compromised

diaphragmatic excursion

Decreased venous return

Decreased cardiac output

Acidosis

Excessive absorption of CO2 results from either excessive

flow and/or excessive pressure. The abdomen can be adequately distended

by pressure in the range of 15-20 mmHg. It is seldom necessary to use an

abdominal pressure greater than 20 mmHg. Little intravasation should

occur at these levels. Pressures over 20 mmHg are virtually never needed

and will increase the amount and rapidity of intravasation. Adequate

respirations help avoid problems related to CO2. The insufflator should

not permit an intra-abdominal pressure that exceeds 30 mmHg

Operative procedures should only be performed with

insufflators capable of flow rates of at least 4-10 l/min. Insufflators

with lower maximum flow rates should only be used for diagnostic

procedures.

Idiosyncratic reactions. In patients with sickle cell

disease or pulmonary insufficiency use of these devices may pose increase

risks of metabolic imbalance related to excessive CO2 absorption.

Hypothermia. High-flow rate insufflators may present a

potential risk for hypothermia.

Precautions

Use of a bacterial hydrophobic filter is strongly recommended

to prevent patient cross-contamination.

Instructions for Use

Clinical Use

Assembly, disassembly, evaluation, care & storage

Cleaning and sterilization

Note: Tubing sets and filters for laparoscopic surgery

should either be provided sterile or include adequate

instruction for sterilization. If they are re-usable,

instructions on how to re-sterilize them must be

provided. Disinfection alone is not adequate.

If applicable, provide test data showing the effects of

repeated sterilization on reusable filters.

Hysteroscopic Insufflators

I. Intended Use

Identify the intended use of the device, being as specific as possible.

For example:

This device is intended to distend the uterus by filling the

uterine cavity with a liquid or gas to facilitate viewing with a

hysteroscope (21 CFR 884.1700).

II. Description of Insufflator

A. Physical and/or Electronic Description

1. Provide a diagram illustrating the flow of gas/liquid from

its source to the exit port of the scope. Include all safety features

and any filters.

2. Indicate whether the device regulates and/or displays each of

the following parameters:

Displays Regulates

Intrauterine Pressure

Flow Rate

Volume Delivered

Net Volume

3. Distension Media

a. If the distension medium gas (CO2) or liquid?

b. What is the reservoir type?

4. Filter (If applicable)

For gas hysteroscopic insufflators, use of a hydrophobic

filter between the patient and the insufflator to prevent patient

cross-contamination is highly recommended. The following specifications

for the filter should be provided:

a. pore size (0.2 micron or less)

b. type

c. materials, including casing and filter material

d. location

5. Tubing (If applicable)

The following specifications for the tubing should be

provided: dimensions and materials for tubing and connectors. Generally

accepted materials for the tubing include silicone or PVC (most common).

Note: If the insufflator is intended for both hysteroscopic and

laparoscopic insufflation ( or hysteroscopic insufflation and

laparoscopic irrigation), you should provide the following information:

A detailed discussion of the redundant fail-safe mechanisms that

your device employs to insure that the device is not inadvertently used

for the incorrect procedure. Inadequate fail-safe mechanisms will

result in product clearance delays.

B. Full Listing of Performance Specifications

1. Provide bench data illustrating the intrauterine pressure

developed by your device at various output pressures and flow rates. If

your device is capable of applying suction, collect test data for both

the "no-suction" and the "maximum suction" scenarios. Your testing

should include at least three different make/models of hysteroscopes.

2. Please describe how your device controls intrauterine

pressure and/or flow rate. Sketches of flow rate and intrauterine

pressure versus time for both the filling phase and the steady state

phase are extremely helpful. If your device measures volume or net

volume delivered to patient, please describe how these measurements are

made.

3. Indicate the maximum and default values for each of the

following parameters.

Default Maximum

Intrauterine \*

Pressure (mmHg)

Flow rate (cc/min) \*\*

Output pressure

(mmHg)

\* For both liquid and gas insufflators, maximum sustained

intrauterine pressure should not exceed 150 mmHg. Since pressures

greater than 100 mmHg are rarely needed, manufacturers are encouraged to

develop insufflators that require positive action on the part of the user

to increase pressure above 100 mmHg.

\*\* We have currently cleared for marketing liquid

hysteroscopic insufflators with maximum flow rates up to 450 cc/min.

Submissions with maximum liquid flow rates above these levels must

include test data demonstrating that the higher flow rates do not

adversely affect safety and effectiveness. Maximum flow rates for gas

hysteroscopic insufflators may not exceed 100 cc/min.

4. Description of key safety features. Indicate which features

are implemented by hardware and which are implemented by software. Some

recommended features are:

a. Overpressure protection

(1) Pressure overshoot not to exceed 150 mmHg for more

than 15 seconds during initial distension.

(2) Pressure relief at max pressure or when patient

pressure exceeds set pressure by more than 5 mmHg for more than 5 sec.

(3) Continuous, non-defeatable audible alarm and visual

indicator at maximum pressure. 5 second delay allowed; temporary

disabling not to exceed 30 seconds

b. A venting mechanism to prevent over-pressurization is

advantageous.

c. Supply tank (gas hysteroscopy)

(1) The supply tank connection should be pin-indexed to

guard against inadvertent use of N2O, regardless of whether the device

allows use of this media.

(2) Front panel should display the amount of gas

remaining in the supply tank, and a visual/audible alarm should warn the

user when the level falls below some reasonable value.

d. Monitoring of the volume of gas/fluid delivered is

desirable.

C. System Level Hazard Analysis

The system level hazard analysis should identify each potential

patient hazard, the cause of the hazard, the level of concern, and the

steps taken to address the potential hazard. Common hazards include:

over-pressurization, intravasation, electric shock, and electromagnetic

compatibility.

D. Software

Insufflators that are software-controlled may be either minor or

moderate concern devices, depending on the design of the particular

device. The guidance document "Reviewer Guidance for Computer

Controlled Medical Devices" discusses ODE's general requirements for

software documentation. You should pay particular attention to the

following elements:

1. Structure chart or flow chart describing software

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2. Summary of software development procedures, including change

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3. Software Requirements Specification (ref IEEE/ANSI 830-1984),

with traceability back to the Hazard Analysis

4. Verification and Validation Test plan, including Pass/Fail

criteria and traceability back to the requirements

5. System level test results

6. Signed certification that "Software development was followed,

that good quality assurance procedures were adhered to, and that test

results demonstrate that the system specifications and the functional

requirements were met".

7. Software version number and date

E. Electrical safety

The submitter should provide either:

Certification that the device complies with

applicable electrical safety standards (e.g., IEC 601-1, UL 544, UL

2601); or

Test results which guarantee a similar level of

protection.

F. Electromagnetic compatibility.

The submitter should provide either:

Certification that the device complies with

applicable standards for Immunity and Emissions (such as CISPR 11, IEC

601-1-2); or

Test results which guarantee a similar level of

protection; or

Justification for why this information is unnecessary

(e.g., due to device design or working conditions).

III. Comparison Table

Provide a table that lists the similarities and differences between

your device and the predicate devices(s). The table should include:

intended use, design features, maximum flow rate, maximum intrauterine

pressure, important safety features, and any other relevant device

characteristics.

IV. Labeling

A. Gas Hysteroscopic Insufflation

Indications for Use

This device provides CO2 gas distension of the uterus for

diagnostic and operative hysteroscopy. See the operators manual of your

hysteroscope for specific indications for use.

Contraindications for use

Use of this device for intrauterine distension is

contraindicated whenever hysteroscopy is contraindicated. See the

operators manual of your hysteroscope for absolute and relative

contraindications.

Operative hysteroscopy. Gas emboli and cardiac arrest have

been reported during hysteroscopic laser and electrosurgical procedures.

Because of the increased risk of gas embolization during operative

hysteroscopy, this device should not be used for such procedures.

Warnings

This device is ineffective for laparoscopic insufflation - it

should not be used for intra-abdominal distension.

Metabolic Acidosis and Resultant Cardiac Irregularity.

Excessive absorption of CO2 results from either excessive

flow and/or excessive pressure. The uterine cavity can be adequately

distended by pressure in the range of 35-75 mmHg. It is seldom necessary

to use an intrauterine pressure greater than 75 mmHg or a flow rate

greater than 100 cc/min. Little intravasation or tubal passage should

occur at these levels. Pressures over 100 mmHg are virtually never

needed and will increase the amount and rapidity of intravasation and

tubal passage of gas. Adequate respirations help avoid problems related

to CO2.

Idiosyncratic reactions.

In patients with sickle cell disease or pulmonary

insufficiency use of these devices may pose increase risks of metabolic

imbalance related to excessive CO2 absorption.

CO2 Embolization.

Risk of CO2 embolism increases with CO2 flow rate. As such,

insufflators should not be used above 100 ml/minute.

Note: Your insufflator should be calibrated not to

exceed 100 ml/minute.

Rupture of a Fallopian Tube Secondary to Tubal Obstruction. This

is generally due to increased pressure above 150 mmHg.

Note: Your insufflator should not exceed this level.

Instructions for Use

Clinical Use

Assembly, disassembly, care & storage

Cleaning and sterilization

Note: Tubing sets and filters for hysteroscopic surgery

must be provided sterile, and if they are re-usable, instructions on how

to re-sterilize them must be provided. Disinfection alone is not

adequate.

If applicable, provide test data showing the effects of

repeated sterilization on reusable filters.

B. Liquid Hysteroscopic Insufflation

Indications for Use

This device provides liquid distension of the uterus for

diagnostic and operative hysteroscopy. See the operators manual of your

hysteroscope for specific indications for use.

Contraindications for use

Use of this device for intrauterine distension is

contraindicated whenever hysteroscopy is contraindicated. See the

operators manual of your hysteroscope for absolute and relative

contraindications.

Warnings

If a liquid distension medium is used, strict fluid intake

and output surveillance should be maintained. If a low viscosity liquid

distension medium is used, intrauterine instillation exceeding 2 liters

should be followed with great care due to the possibility of fluid

overload.

(If applicable) If a high viscosity fluid (e.g., Hyskon) is

used, the use of more than 500 ml should be followed with great care.

See labeling for Hyskon for additional information.

Intrauterine distension can usually be accomplished with

pressures in the range of 35-75 mmHg. Unless the systemic blood pressure

is excessive, it is seldom necessary to use pressures greater than 75-80

mmHg.

Complications may include:

Hyponatremia. Intravasation of some distension fluids

may lead to fluid overload and, consequently, hyponatremia with its

attending sequelae. This can be affected by the distending pressure, flow

rate, and duration of hysteroscopic procedure. It is critical to closely

monitor the input and outflow of the distending liquid.

Hypothermia

Pulmonary Edema

Idiosyncratic Reaction. (Intravascular coagulopathy;

allergic reaction, including anaphylaxis)

Rupture of a Fallopian Tube Secondary to Tubal

Obstruction. Cerebral Edema

Instructions for Use

Choice of distension media:

1. Conductive vs. Non-Conductive Media

When performing hysteroscopic electrosurgery,

the distension medium must be electrically non-conductive. Examples

include D5W, glycine, sorbitol, mannitol, sorbitol plus mannitol, and

dextran.

2. Low Viscosity vs. High Viscosity Media

Assembly, disassembly, care & storage

Cleaning and Sterilization

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