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 VERSION
NEURO ENDOSCOPE GUIDANCE

Prepared By:

Neurological Devices Branch
Division of Cardiovascular, Respiratory and Neurological Devices
Office of Device Evaluation

Draft - July 7, 1994
(reformatted 12/17/97)

(To be used in conjunction with Draft DCRND 510(k) Guidance)

This guidance document may contain references to addresses and telephone numbers that are now obsolete. The following contact information is to be used instead:

- **While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration to the General Surgical Devices Branch, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850.**
- **For questions regarding the use or interpretation of this guidance, contact the General Surgical Devices Branch at 301- 594-1307.**
- **To contact the Division of Small Manufacturers Assistance (DSMA), call 800-638-2041 or 301-443-6597; fax 301-443-8818; email dsmo@cdrh.fda.gov; or write to DSMA (HFZ-200), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307. FACTS-ON-DEMAND (800-899-0381 or 301-827-0111) and the World Wide Web (CDRH home page: http://www.fda.gov/cdrh/index.html) also provide easy access to the latest information and operating policies and procedures.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

•**INTRODUCTION** This document is intended to be used in conjunction with the general information outlined in the "**Draft - DCRND 510(k) Guidance.**" This document outlines specific information to be submitted for neurological endoscopes. For endoscopes that differ significantly from those already on the market in either specifications or intended use, FDA may require additional information specific to those differences.

•**Overview** A neurological endoscope is described in the FDA regulations, 21 CFR 882.1480 as an instrument with a light source used to view the inside of the ventricles of the brain. Hazards identified during initial classification of this device by the advisory panel included issues related to sterility and the potential for burns. The advisory panel classified the device as a class II (special controls). The panel recommended that a standard should cover optical distortion and should be limited so that the field of view is faithfully reproduced and that the device should be subject to an electrical standard because it makes contact with body fluids. Risks to health included infection, burns and electrical shock potential.

Examples of devices within this generic type include endoscopes that are both rigid and flexible; reusable (multi-use) and disposable (single use); that can be used with direct visualization; and/or can be used with assisted vision such as a video camera. Examples of accessories that assist or increase the versatility of the endoscope include devices which permit the user to obtain diagnostic information or perform a therapeutic function such as scissors, biopsy forceps, cameras, etc.

SUGGESTED FORMAT and CONTENT - **See DCRND 510(k) draft guidance**

- **General information** - **see DCRND 510(k) draft guidance**
  - Trade name
  - Common name
  - Establishment registration Number
  - Address of manufacturing facilities
  - Classification
  - Identification of predicate device
  - Compliance with standards or guidelines

- **Summary and/or certification statement in accordance with SMDA** - **see DCRND 510(k) draft guidance**

- **Labeling** - **see DCRND 510(k) draft guidance.**
  - Identification labels
  - Intended use and directions for use including instructions for care, cleaning and sterilization of the equipment. This is required for the scope and all accessory equipment.
  - Advertisements.
  - Prescription labeling in accordance with 21 CFR 801.109 (b)(1).
  - A functional description of the scope and all required accessory instrumentation needed to perform the procedure including video equipment, monitors, cables etc.

In addition:

- Provide all labeling including advertisements, appropriate directions for reprocessing/ disinfection/sterilization, maintenance, etc. Include all cautions, warnings, precautions, contraindications or limitations.

- If a reusable scope, provide a warning/contraindication within the labeling that this should not be used in patients suspected of having Creutzfield-Jakob Disease (CJD).

- Functional test procedures for the endoscope prior to use would be provided in the users guide. Maintenance/trouble-shooting procedures should be outlined with instructions on how to perform the maintenance, frequency, replacement parts ("O" rings) and instructions for the purchase of replacement parts.

- Irrigation
  - Provide specific directions for use of any saline infusion.

- Suction
  - Provide adequate directions for the regulation of suction to the apparatus.

- Sterilization instructions. The sterilization should not compromise the optical and mechanical performance of the device.
  - The user should be given guidance on the expected lifetime of the device through the number of reuse/cleaning/sterilization cycles to which it may be exposed. Provide the intervals for routine maintenance and failures or deterioration signaling the need to repair or discard the device.
  - Detailed reprocessing instructions must be provided and should address sterilization, as well as the following:
    - Assembly/disassembly
    - Detailed cleaning

  NOTE: Cold chemical sterilization of the scope is acceptable only for terminal disinfection and is <u>UNACCEPTABLE</u> for sterilization. Labeling should specify this.

- **Detailed physical device description** - **see DCRND 510(k) draft guidance.** In addition provide the following specifically related to neuroendoscopes:

  A detailed physical description of each device, model and all accessories including but not limited to fixation devices, biopsy instruments, scissors, punch forceps, coagulating instruments, etc.

  - Schematic and engineering drawings
    - Rigid endoscopes should include a labeled schematic of the scope, assembled and unassembled, including the name and function of all parts.
    - Enlarged drawings and descriptions of all tip configurations should be provided indicating any limitations of use with the intended scope.

  - Accessories
    - Describe the specifications of all accessories. In particular describe any accessories (such as greenberg, budde or other retractor system) to be used which will assist in the fixation of the scope to prevent accidental motion movement or plunges. With coagulating instruments provide assurance that there is no potential for accidental coagulation of adjacent brain tissue along the path of the scope from a break in the insulation.

Specifications -

- Diameter
- Length, (working and total)
- Number and sizes of lumens
- Field of view - (in air and in water)
- Depth of field or working distance (mm) and the F# of the objective lens at optimum working distance.
- Magnification of objective lens, eyepiece, and relay lens.
- Change in the focal length, if any (e.g., zoom feature, eyepiece magnification).
- Materials (include adhesives and solders)
- Lens description
- Describe the deflectability of flexible scopes in terms of the range and length of the flexible section.

  Complete description of deflecting mechanism cables, wires, etc.(description of testing of mechanism to failure)
- Detailed engineering drawings showing all pertinent features of the scope and accessories.
- Identify light source, provide thermal measurements in an enclosed (5ml), static CSF environment at point of greatest heat production (endoscope tip or focal point). Testing must replicate the actual anatomical presentation.
- Provide technical specifications including electrical and insulating safety features.
- Image quality - Provide information on the image quality obtainable with the subject endoscope. Given below are two options for meeting this requirement: Spatial resolution or Modulation transfer function (MTF) data. In some special cases (e.g., three dimensional imaging, it may be necessary to provide the results from MTF testing. This section on image quality is still under development. FDA reviewers will consider reasonable alternatives to these two options.
  - Resolution (mm)
    - Compare the resolution of your device to a predicate. Resolution using the USAF bar pattern would be an acceptable method of measurement for comparison. This test setup should have the bar pattern on axis, and should optimize the magnification and illumination.
    - The endoscope should be able to resolve the 5.0 USAF bar pattern (bars spaced at 200m, i.e., more than 5 lines/mm).
  - Modulation Transfer Function (MTF)
    - Provide a description of the system MTF over relevant spatial frequencies. This test setup should have the bar pattern on axis and should optimize the magnification and illumination.

- Distortion characteristics (compensation)
  - Provide information on the distortion introduced by the fiberoptics and objective lens combination. As an example, this could be provided by imaging a piece of graph paper and providing a comparison of the paper and the photographed image of the graph paper. If the distortion is corrected by signal processing, provide the resulting, corrected image of the graph paper.
- Environmental effects on optical performance
  - Baseline
    - Provide a transmission spectrum of the optical system between 400 nm and 700 nm (the human vision band) to be used as a baseline. This baseline should represent a typical use situation. Since heating effects can change the

transmission spectra of fiberoptics, the measurement should reflect a minimal 2 hour duration that the scope might be in use.
    - N.B. Neither UV not IR is required for visualization, but UV can deteriorate optics and produce fluorescence, and IR will cause unwanted heating.
- Changes during or as a result of storage, use and sterilization.
    - If solarization or tinting effects, aging effect, or effects due to irradiation (either through light or radiation used in sterilization or sterilization procedures) produce a change in the fiber transmission, show that this does not impair its intended use.
    - Storage and/or usage should not impair the performance over an intended lifetime.
    - Reprocessing/refurbishing should not impair the performance over repeated use.
- Color
    - Show that the fiber transmission produces colors sufficient for use in diagnosis.
    - If the device is intended for repeated use, show that its transmission remains stable (with regard to color transmission) after the intended number of sterilization and use cycles. Transmission of sufficient color for diagnosis is of primary concern - i.e., inflamed tissue should appear inflamed, not normal.

- Specific optical performance characteristics
    - Rigid rod-lens systems
        - Lens diameters (mm)
        - Endoscope length (mm) and diameter (mm).
          Length and diameter must correspond to intended clinical use.
    - Fiberoptic imaging system
        - Total number of fibers
        - Fibers per square millimeter
        - Size of fiber core (mm)
        - Area of active fiber per square millimeter
    - Electronic video imaging system
        - Total number of pixels
        - Pixels per square millimeter
        - Size of pixel (nm)
        - Active area of CCD chip (mmxnm)
    - Illumination
        - Identification of source
          (*) Type of source (e.g., Quartz, Xenon)
          (*) Emission bandwidth (nm)
          (*) Power rating of source (watts)
        - Illuminating delivery fiber
          (*) Number of fibers
          (*) Transmission bandwidth (nm)
          (*) Size of fiber core
          (*) Fiber configuration
          (*) Color modification in transmission
        - Level of illumination delivered
          (*) Control of the level of illumination should be provided to optimize the image. UV and IR are harmful to fiber optics systems and tissues and their transmission should be minimized.
          (*) Provide the minimum and maximum level of illumination (lumens).

      NOTE - If new illumination sources are used, additional information may be needed.

    - Electronics, software/firmware including video couplers, enhancement and display instrumentation.

Provide an overview including block diagrams of all electronic components of the endoscope imaging system. Where appropriate, refer to *FDA's Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review*. The overview should address the following concerns

- System components - use of Off-the-Shelf Equipment Labeling should provide all required specifications.

  Where the device has used components previously cleared under 510(k), provide the 510(k) number of the other submission
- Electrical/optical compatibility
  (*) Effects of optical components to overall image transmission.
  (*) Effects of electrical components to overall image transmission.
- System components: Subject of this submission
  (*) Complete description of system
  (*) Software as applicable
  (*) Image degradation
- Image display
  (*) Two dimensional display
    (+) Description of the display (CRT, LCD, Plasma display, etc.)
    (+) Resolution of the display (TV lines/picture height)
  (*) Three Dimensional display
    (+) Description of the display (CRT, Goggles, etc.)
    (+) Resolution of the display (TV lines/picture height, width, depth)
    (+) Provide measurement of depth resolution (Is perceived depth linear with varying object distance?)

- Mechanics - The information provided for system mechanics should address changes that occur as a result of sterilization and/or other reprocessing expected during use.
  - Description of mechanics of the neuroscope and individual mechanical systems as applicable
    (*) Bending mechanism and its control
    (*) Fluid delivery system and its control
    (*) Any other mechanical systems or controls
  - Mechanical strength - (this section is still under development)
  - Mechanical integrity - (this section is still under development)

- Electrical safety
  - Isolation from patient and physician
  - Use with other devices such as laser and electrical safety instruments
    (*) Some devices pose a risk potential from capacitive coupling, e.g., irrigation/suction probes with electrical surgical capabilities. The 510(k) should address this risk, relative to comparable devices. Refer to AGL's electrical safety statement (Reference).
    (*) For general safety requirements specific to electrosurgical devices refer to the ANSI/AAMI standard for electrosurgical devices (Reference).

It may be useful to reference, as appropriate, the IEC standard on electrical safety of medical instruments, UL-listing or the draft IEC standard on safety of endoscopic equipment.

- Thermal safety
    - Address endoscope heating as it relates to illumination.
      Discuss the safe use of the endoscope with all recommended illumination sources. Provide data to demonstrate safety.
    - Identify light source, provide thermal measurements in enclosed (5ml), static CSF environment at point of greatest heat production (endoscope tip or focal point).
    - If thermal measurements are greater than $2^{o}C$, provide justification and assurance that the temperature rise will be non injurious to the adjacent neuro tissues.

- Irrigation safety
    - Provide testing to document that sufficient margin of safety exists in the egress of fluid irrigated into the surgical field.
    - Provide a risk analysis of the potential for increased ICP with the use of irrigation.

- Suction safety
    - Provide a risk analysis of applying too much suction to the surgical field and describe how potential complications will be alleviated in the use of suction.

The above physical descriptions should include any significant changes or modifications to the scope or accessories from the predicate device that could affect the safety, effectiveness or intended use of the device.

- **Comparative information - see DCRND 510(k) draft guidance**
  In addition the following must be provided in side by side tabular form:

  - Predicate device physical description comparison.
    - Identify predicate device with same intended use and make comparisons.
    - Provide side by side comparisons in chart form including similarities and differences.
    - Explain the consequences and effects of changes or modifications and how the differences affect the use and safety of the device.
    - Comparisons in physical description, materials, dimensions, etc.

- **Biocompatibility - see DCRND 510(k) draft guidance**
  - In addition provide the following additional information:
    - Describe if all materials (including adhesives and solder) have been evaluated according to the recommendations of the Tripartite Guidance. All testing must be performed on the final sterilized device. If certain tests were not performed, provide sufficient scientific justification for not performing the tests.

- **Sterilization Information - see DCRND 510(k) draft guidance**
  - Method used to provide sterility assurance, if applicable.
  - Shelf life testing and accelerated aging testing.
  - Provide bench testing to document sterilizability of the device under conditions of use in an institutional setting.
    - Provide inoculation microbiological testing of a representative number of reusable scopes and subsequent decontamination, cleaning, resterilization to document that the recommended reprocessing techniques be adequate.

- **Software Validation - see DCRND 510(k) draft guidance**
  - See Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review.

- **Standards**

  Document all standards with which your device is in compliance (ISO/DIS 8600, OIEC 601-1, UL 544, Tripartite Biocompatibility Guidance for Medical Devices, etc.) and how it complies or fails to comply with the standards. Provide scientific justification and implications where your device fails to comply with these established guidelines.

References

1. Martin, Dan C.: Soderstrom, Richard M,; Hulka, Jaroslav F. (Ad Hoc Committee on Electrocautery). Electrical Safety [Statement]. American Association of Gynecologic Laparoscopists; 1992 April 21.

2. International Electrical Commission. Medical Electrical Equipment, Part 2; Particular Requirements for the Safety of Endoscopic Equipment [Draft Standard]. IEC Publication 601-2-18. April 6, 1993

3. Martin, Dan C.: Holtz, Gary L.; Levinson, Carl J.; Soderstrom, Richard M.; eds. Manual of Endoscopy [Manual]. American Association of Gynecological Laparoscopists; 1990.

4. Association for the Advancement of Medical Instrumentation. American National Standard for Electrosurgical Devices [Standard]. ANSI/AAMI HF18-1986. September 1986.

5. International Electrotechnical Commission. Medical Electrical Equipment. Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment [Standard]. IEC Publication 601-2-2. March 15, 1990.

6. Zafra V. Letter to: Laparoscope and Endoscopic Coagulator Manufacturers. 1980 July 28. 1 leaf.

7. FDA's Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review.

CHECK OFF SHEET
NEURO ENDOSCOPE GUIDANCE

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In addition:

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Specifications -
____ - Diameter
____ - Length, (working and total)
____ - Number and sizes of lumens
____ - Field of view - (in air and in water)
____ - Depth of field or working distance (mm) and the F# of the objective lens at optimum working distance.
____ - Magnification of objective lens, eyepiece, and relay lens.
____ - Change in the focal length, if any (e.g., zoom feature, eyepiece magnification).
____ - Materials (include adhesives and solders)
____ - Lens description
____ - Describe the deflectability of flexible scopes in terms of the range and length of the flexible section.

Complete description of deflecting mechanism cables, wires, etc.(description of testing of mechanism to failure)

____ - Detailed engineering drawings showing all pertinent features of the scope and accessories.
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____ - Environmental effects on optical performance
____ - Baseline
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____ (*) N.B. Neither UV not IR is required for visualization, but UV can deteriorate optics and produce fluorescence, and IR will cause unwanted heating.

____ - Changes during or as a result of storage, use and sterilization.
____ (*) If solarization or tinting effects, aging effect, or effects due to irradiation (either through light or radiation used in sterilization or sterilization procedures) produce a change in the fiber transmission, show that this does not impair its intended use.
____ (*) Storage and/or usage should not impair the performance over an intended lifetime.
____ (*) Reprocessing/refurbishing should not impair the performance over repeated use.

____ - Color
____ (*) Show that the fiber transmission produces colors sufficient for use in diagnosis.
____ (*) If the device is intended for repeated use, show that its transmission remains stable (with regard to color transmission) after the intended number of sterilization and use cycles. Transmission of sufficient color for diagnosis is of primary concern - i.e., inflamed tissue should appear inflamed, not normal.

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____ - Rigid rod-lens systems
____ (*) Lens diameters (mm)
____ (*) Endoscope length (mm) and diameter (mm).
____ Length and diameter must correspond to intended clinical use.

____ - Fiberoptic imaging system
____ (*) Total number of fibers
____ (*) Fibers per square millimeter
____ (*) Size of fiber core (mm)
____ (*) Area of active fiber per square millimeter

____ - Electronic video imaging system
____ (*) Total number of pixels
____ (*) Pixels per square millimeter
____ (*) Size of pixel (nm)
____ (*) Active area of CCD chip (mmxnm)

____ - Illumination
____ (*) Identification of source
____ (+) Type of source (e.g., Quartz, Xenon)
____ (+) Emission bandwidth (nm)
____ (+) Power rating of source (watts)
____ (*) Illuminating delivery fiber
____ (+) Number of fibers
____ (+) Transmission bandwidth (nm)
____ (+) Size of fiber core
____ (+) Fiber configuration
____ (+) Color modification in transmission
____ (*) Level of illumination delivered
____ (+) Control of the level of illumination should be provided to optimize the image. UV and IR are harmful to fiber optics systems and tissues and their transmission should be minimized.
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NOTE - If new illumination sources are used, additional information may be needed.

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____ (+) Effects of optical components to overall image transmission.
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____ (+) Two dimensional display
____ ·) Description of the display (CRT, LCD, Plasma display, etc.)
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____ - Comparisons in physical description, materials, dimensions, etc.

____• **Biocompatibility - see DCRND 510(k) draft guidance**

____ - In addition provide the following additional information:
____ - Describe if all materials (including adhesives and solder) have been evaluated according to the recommendations of the Tripartite Guidance. All testing must be performed on the final sterilized device. If certain tests were not performed, provide sufficient scientific justification for not performing the tests.

____• **Sterilization Information - see DCRND 510(k) draft guidance**

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____• **Software validation - see DCRND 510(k) draft guidance**

____ - See Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review.

____• **Standards**

Document all standards with which your device is in compliance (ISO/DIS 8600, OIEC 601-1, UL 544, Tripartite Biocompatibility Guidance for Medical Devices, etc.) and how it complies or fails to comply with the standards. Provide scientific justification and implications where your device fails to comply with these established guidelines.