

## SUMMARY OF SAFETY AND PROBABLE BENEFIT

### I. GENERAL INFORMATION

Device Generic Name: Transabdominal amnioscope (fetoscope) and accessories

Device Trade Name: Karl Storz Semi-Rigid TTTS Fetoscopy Instrument Set  
Karl Storz Rigid TTTS Fetoscopy Instrument Set with 0 and  
12 degree scope  
Karl Storz Rigid TTTS Fetoscopy Instrument Set with 30  
degree scope

Applicant's Name and Address: Karl Storz Endoscopy-America, Inc.  
600 Corporate Pointe  
Culver City, CA 90230

Humanitarian Device Exemption (HDE) Number: H040005

Date of Humanitarian Use Device Designation: October 7, 2003

Date(s) of Panel Recommendation: None

Date of Good Manufacturing Practice Inspection: November 6, 2003\*  
*\*Only a paper review deemed necessary and  
routine post-approval follow-up*

Date of Notice of Approval to Applicant:

### II. INDICATIONS FOR USE

The Karl Storz TTTS Fetoscopy Instruments Sets are indicated for selective laser photocoagulation (S-LPC) in the treatment of twin-to-twin transfusion syndrome (TTTS) for fetuses whose gestational age is between 16 and 26 weeks.

### III. CONTRAINDICATIONS

The Karl Storz Fetoscopy Instruments Sets are contraindicated for use in S-LPC when the following conditions exist:

- ruptured membranes
- chorioamnionitis
- placental abruption or active labor

The Karl Storz Fetoscopy Instrument Sets are also contraindicated for use when, in the opinion of a qualified physician, such use would create a condition that would be dangerous for the mother or fetus.

Use of the Karl Storz Fetoscopy Instrument Sets is contraindicated whenever endoscopy is contraindicated.

#### IV. WARNINGS AND PRECAUTIONS

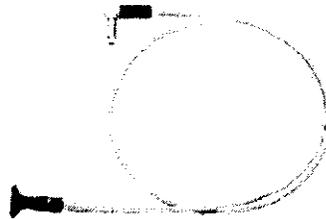
The warnings and precautions can be found in the Karl Storz Fetoscopy Instrument Sets labeling.

#### V. DEVICE DESCRIPTION

The Karl Storz TTTS Fetoscopy Instrument Sets consist of both semi-rigid and rigid sets which include fetoscopes and introductory sheaths. The Karl Storz Semi-Rigid TTTS Fetoscopy Instrument Set includes the following devices:

- semi-rigid fetoscope (model #11630AA)
- a reusable diagnostic sheath (#11605)
- two operating sheaths, one needle-shaped (11630KF) and one with a blunt tip (11630KH)

##### **Semi-Rigid Model #11630 fetoscope**



The Karl Storz Rigid TTTS Fetoscopy Instrument Set with 0 or 12 degree scope includes the following devices:

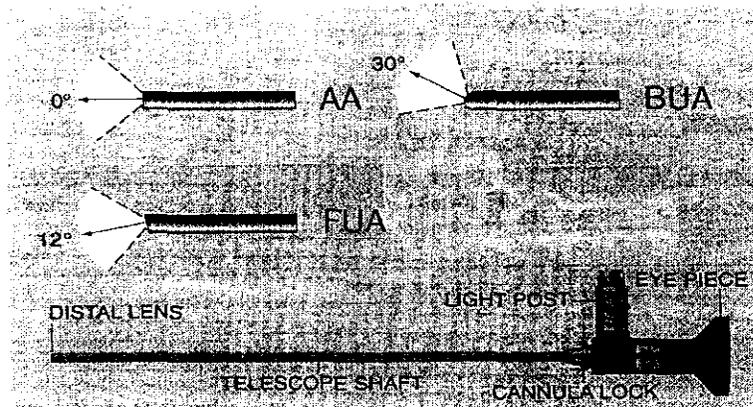
- rigid fetoscope (HOPKINSII® #26008AA and #26008FUA)
- single operating sheath (#26161U)
- a continuous flow operating sheath set (#26262CN and #26161CD)

The Karl Storz Rigid TTTS Fetoscopy Instrument Set with 30 degree scope includes the following devices:

- rigid fetoscope (HOPKINSII® #26008 BUA)
- a standard sheath set (#26161UF and #26161UH)

The following is a picture of the HOPKINSII® fetoscope with the various directions of view:

## HOPKINSII® Model 26008 fetoscope



### Specifications:

Letter code	Direction of View
AA	0° Straight Forward
BUA	30° Forward-Oblique
FUA	12° Telescopes

### Semi-Rigid TTTS Fetoscopy Instrument Set

The semi-rigid fetoscope (#11630AA) is a miniature straight forward telescope (0 degrees). It has a diameter of 2 mm and a working length of 30 cm. This fetoscope is autoclavable. It is designed with a remote eyepiece and incorporates fiber optic light transmission. The semi-rigid fetoscope is compatible with various diagnostic and operating sheaths. The diagnostic fetoscope sheath (#11605) is 28 cm long and has a diameter 3 mm. It includes a 1 mm channel which can accommodate laser fibers with a maximum outer diameter of 900 microns. It also contains a stopcock and a luer-lock adapter for irrigation and drainage of fluid. This sheath is equipped with a pyramidal obturator (#11605FO) for use during direct introduction.

The semi-rigid fetoscope is also compatible with two operating sheaths. Model #11630KF has a length of 25 cm and a diameter 3 mm. It is needle-shaped with a pointed tip. It includes a 1 mm working channel, as well as a stopcock and a luer-lock adapter. Model #11630KH also has a length of 25 cm and a diameter 3 mm. This sheath is needle-shaped with a blunt tip. It includes a 1 mm working channel and a stopcock.

### Rigid TTTS Fetoscopy Instrument Sets

#### *Rigid TTTS Set with 0 or 12 degree scope*

The rigid fetoscope, HOPKINSII® #26008 is a reusable, autoclavable, rod lens telescope available in zero degree (model #26008AA) or twelve degree (model #26008FUA). It has a 2 mm diameter and is 26 cm long. The rigid fetoscope includes an eyepiece lens and a light post connection for fiber optic light cables with screw-on adapters which accommodate light cables from other manufacturers. The shaft is made of non-corrosive material that encloses the rod-lens system and a built-in fiber

optic light carrier. This fetoscope is compatible with a single lumen sheath or a continuous flow sheath. The single lumen rigid sheath (# 26161U) is 23 cm in length. It has an oval shape and its outer diameter is 2.4 mm x 3.5 mm. It incorporates a pyramidal obturator and a 1 mm working channel. It contains a stopcock and a luer-lock adaptor. The continuous flow rigid sheath set consists of an inner (#26161CN) and outer sheath (#26161CD). The outer sheath is a 5 mm continuous-flow fetoscope sheath. It is 19 cm long and contains a 2 mm working channel. It includes a stopcock and a luer-lock adaptor. The inner sheath has a length of 19 cm and a diameter of 4.3 mm. It contains a 1.7 mm working channel.

#### *Rigid TTTS Set with 30 degree scope*

The rigid fetoscope, HOPKINSII® #26008 included in this set is available in 30 degree (model #26008BUA.) It is used with a standard rigid sheath set which consists of an oval outer sheath (#26161UF) and an inner sheath (#26161UH). The outer sheath is 20 cm long and has a diameter of 3.1 mm x 4.3 mm. It incorporates a pyramidal obturator and a channel for use with laser fibers with a maximum diameter of 900 microns. It contains a stopcock and a luer-lock adaptor. The inner sheath is a working insert with a deflecting Albarran steering lever at the tip. This steering level enables deflection of the laser fiber towards the target.

#### *Principle of Operation:*

The Karl Storz TTTS Fetoscopy Instruments Sets are used in fetoscopic laser surgery. The specific instrument sets are for use in the S-LPC of the connecting twin-to-twin blood vessels in TTTS.

The diagnosis of TTTS should be established prior to fetoscopy. Diagnostic criteria include: monochorionic placentation with visualization of a separating membrane, fetuses of the same sex, mid-pregnancy polyhydramnios-oligohydramnios sequence (polyhydramnios at the recipient's sac and oligohydramnios at the donor's sac), in the absence of other causes of abnormal amniotic fluid volume, and marked growth discordance.

In this procedure, the physician will introduce the fetoscopy instruments under ultrasound guidance by one of the following three options:

- with a trocar and cannula combination
- with a sharp-tip obturator and fetoscopy sheath
- with sharp-tip sheath and telescope

The instruments are inserted percutaneously through the maternal abdomen and uterine wall into the amniotic cavity of the recipient twin. After introduction, the fetoscope is either already in place or the trocar/obturator is removed and the fetoscope is inserted into the sheath/cannula. The placenta is surveyed using fetoscopes of the length and viewing angle preferred by the physician. The communicating vessels connecting recipient twin to donor twin are identified. A 600µm laser fiber is introduced through the instrument channel of the sheath to ablate the connecting vessels.

At the end of fetoscopic surgery, excess amniotic fluid may be removed from the

recipient twin.

## VI. ALTERNATIVE PRACTICES OR PROCEDURES

The following alternative practices and procedures are currently available treatments for TTTS:

### Serial Amniodrainage

Serial amniodrainage is historically the most established and most commonly used method used to treat twin-to-twin transfusion syndrome. It is done to prevent polyhydramnios-related miscarriage by removing excess fluid from the recipient's sac. The underlying paradigm is that a decrease in pressure will allow both twins the chance for a longer gestation period and greater likelihood of survival. Amniodrainage is repeated as necessary depending on the rate of re-accumulation of fluid in the recipient's sac. Perinatal survival rates vary widely between 15-82%<sup>1</sup>, while reported neurological abnormalities are between 18 and 22%. The risks of amniodrainage as a TTTS treatment technique include infection, membrane rupture, preterm labor, chorioamnionitis, and placental abruption due to sudden pressure decompression.

### Septostomy

Septostomy is based on the assumption that intra-amniotic pressure is increased in the recipient's sac but decreased in the donor's sac. Creating a "window" in the inter-twin membrane between recipient and donor, should cause the fluid to move towards the donor's amniotic cavity and restore the balance in fluid levels, thus resolving the oligohydramnios of the donor. A 20-22 gauge needle is used to perforate the interfetal membrane septum through repeated piercings from the needle. This creates pseudo-monoamniotic twins. Possible complications include preterm labor, placental abruption, and cord entanglement.

### Selective Feticide

Selective feticide is based on the theory that stopping transfusion or shunting from the live twin to the dead twin will save the life of the survivor (who would likely have died anyway.) It is used in severe cases where spontaneous fetal death is likely to occur and the fetus selected is the one with the most severe complications, such as hydrops or severe growth restrictions. It is intended to increase the chance of survival for the remaining twin. Techniques used for cord occlusion include cord embolization, Nd:YAG laser technique, cord ligation, and bipolar coagulation.

### Pregnancy Termination

Termination of the pregnancy prior to 24 weeks is an option that is rarely suggested to patients nor is it regularly utilized unless both fetuses are in severe distress.

## VII. MARKETING HISTORY

The Karl Storz Fetoscopy Instrument Sets are currently being marketed in Europe, Eastern Europe, the Middle East, Asia, Japan, Australia, Canada and South America.

The Fetoscopy Instrument Sets have not been withdrawn from marketing for any reason relating to their safety or probable benefit.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

*Observed Adverse Effects*

A total of 142 patients were enrolled in a randomized, controlled, clinical trial comparing selective laser photocoagulation (S-LPC) of anastomoses using the Karl Storz Fetoscopy Instrument Sets to serial amnioreduction in the treatment of TTTS<sup>1</sup>. Safety was assessed through the occurrence of maternal complications and fetal complications. Table 1 summarizes the adverse events observed in this study:

**Table 1 - Maternal and Obstetrical Complications**

	Laser N=69	Amnioreduction N=68	p-value
Placental abruption	1/69 (1%)	2/68 (3%)	0.62
Intraabdominal leakage of amniotic fluid†	2/69 (3%)	0	0.50
Pregnancy loss within 7 days after initial procedure	8/69 (12%)	2/68 (3%)	0.10
Preterm rupture of membranes (PROM) within 7 days of initial procedure	4/69 (6%)	1/68 (1%)	0.37
Preterm rupture of membranes(PROM) and fetal death within 7 days of procedure	4/69 (6%)	1/68 (1%)	0.37
PROM and fetal death within 28 days of procedure	6/69 (9%)	6/69 (9%)	0.98
	N=138	N=136	
Intrauterine death within 7 days of initial procedure	16/138 (12%)	9/136 (7%)	0.23

† Abdominal pain related to intraabdominal leakage of fluid through the uterine puncture was managed expectantly and resolved in the two women in the laser group.

*Potential Adverse Effects*

Although not reported during the randomized, clinical trial, other potential adverse effects associated with the Karl Storz Fetoscopy Instrument Sets may include:

Maternal Complications

- Wound infection
- Chorioamnionitis
- Chorioamniotic separation
- Amniotic fluid embolism
- Bleeding/hemorrhage
- Complications from severe bleeding
- Inability to have future children
- Hysterectomy
- Maternal death

- Complications/side-effects of anesthesia (epidural anesthesia and general anesthesia)
- Pre-term labor
- Mirror Syndrome

#### Fetal Complications

- Chorioamniotic separation
- Neurological complications or other forms of brain damage may occur (such as subchorionic hematoma)
- Complications of prematurity
- Fetal injury during entry due to accidental penetration of the placenta by instruments
- Morbidity after birth
- Incomplete coagulation of communicating vessels
- Subchorionic hematoma
- Ileal atresia
- Limb necrosis
- Congenital skin loss
- Need for transfusion of one or both fetuses
- Need to sacrifice one fetus in order to save the other
- Fetal bradycardia

## IX. SUMMARY OF PRECLINICAL STUDIES

### *Biocompatibility*

The patient contacting materials used in the Karl Storz Fetoscopy Instrument Sets have been used by Karl Storz for years in their marketed endoscopes. Karl Storz provided an acceptable justification for not conducting new biocompatibility testing on the patient contacting materials of the fetoscopy instrument sets. This justification was based on a long and safe history of use in other endoscopes marketed by Karl Storz, an examination of the historical use of the materials in surgical implants over the past 10 years, and a review of the Material Safety Data Sheets (MSDS) provided for the materials. It was therefore determined that the manufacturer has satisfied the requirement for establishing the safety of these materials.

### *Sterility*

The Karl Storz Fetoscopy Instrument Sets components, i.e., fetoscopes and sheaths are not provided sterile. They are designed to be cleaned and sterilized by the user prior to use. The labeled sterilization methods, i.e., steam, STERIS, and STERRAD, have been validated in accordance with AAMI guidelines (AAMI TIR 30:2003 and AAMI TIR 12:1994) to provide a sterility assurance level (SAL) for the device of at least  $10^{-6}$ .

### *Electrical Safety and Electromagnetic Compatibility*

Testing of the Karl Storz Fetoscopy Instrument Sets for electrical safety and/or electromagnetic compatibility was not required based on the design and instructions for use.

## ***Design and Performance***

### Optical Testing

Optical testing was performed which included optical performance, illumination performance and environmental effects. The optical performance testing included field of view, direction of view, resolution, distortion, eyepiece magnification and focal length. Illumination performance testing included the maximum and minimum output.

### Thermal Safety

Thermal safety was assessed by examining the temperature versus time for a semi-rigid fetoscope operated in room air for a period of 2 hours. The resulting values are within the maximum acceptable temperatures set forth in part 42 of IEC 601-2-18 “Particular Requirements for the safety of endoscopic equipment.”

### Cleaning Validation

Several validation studies were conducted to show that the recommended cleaning instructions included in the professional labeling are effective in reducing the bioburden, and the levels of blood and proteins to an acceptable level.

## X. SUMMARY OF CLINICAL INFORMATION

### **Eurofetus Clinical Trial<sup>1</sup>**

**Purpose:** To compare the safety and efficacy of two different treatment methods in severe TTTS before 26 weeks 0 days gestation. The study was designed to examine whether selective laser photocoagulation (S-LPC) of anastomoses using the Karl Storz TTTS Fetoscopy Instrument Sets, is superior to serial amnioreduction in the treatment of TTTS. (Published studies on laser photocoagulation in the treatment of TTTS have highlighted a distinction between non-selective and selective laser photocoagulation between communicating vessels.<sup>2</sup> In the Eurofetus study, S-LPC was performed.)

#### **Endpoints:**

The primary outcome measures, included:

- Perinatal (within 28 days) survival of at least one twin
- Survival of at least one twin to 7-12 months of age
- Clinically significant neurologic complications (i.e., severe intraventricular hemorrhage (grade III or IV), cystic periventricular leukomalacia, blindness and deafness) at 7-12 months of age.

Secondary outcome measures included:

- maternal and obstetrical complications associated with either treatment
- fetal complications

**Methods:** A prospective, randomized (1:1), open-labeled, multi-center, international study was conducted at seventeen centers in 6 countries. Pregnant women with severe TTTS between 15 and 26 weeks gestation were randomly assigned to S-LPC or serial

amnioreduction. While all centers performed amnioreduction, only 3 of the 17 centers with the appropriate Karl Storz equipment performed S-LPC. The equipment used included the Karl Storz miniature semi-rigid 11630 telescope (and associated sheaths), along with a neodymium:yttrium-aluminum-garnet (Nd:YAG) or diode laser with a fiber diameter of 400-600 microns, with laser power output between 30-60W. The study included 142 patients diagnosed with TTTS. Study subjects were required to meet the following inclusion/exclusion criteria:

**Inclusion Criteria**

- Pregnant women between 15 and 26 weeks gestation with severe TTTS
- Polyuric polyhydramnios in the recipient twin with the deepest vertical pool measuring at least 8.0 cm at or before 20 weeks gestation or 10.0 cm after 20 weeks gestation
- A distended fetal bladder in the recipient twin
- Oliguric oligohydramnios in the donor twin, with the deepest vertical pool measuring at most 2.0 cm

**Exclusion Criteria**

- Fetal death
- A major fetal anomaly
- Ruptured membranes
- A maternal condition mandating delivery
- Any previous invasive therapy for the syndrome

The S-LPC procedure was completed with amnioreduction, removing fluid to levels at or just below normal.

**Interim Analyses:** The study design included two interim analyses after enrollment of 72 and 144 women. The purpose of the interim analyses was to evaluate the rate of survival of at least one twin to discharge from the neonatal intensive care unit (NICU).

**Demographics:** Table 2 summarizes important demographic information:

**Table 2** -- Patient Demographics

	S-LPC (N=72)	Amnioreduction (N=70)
Gestational age at randomization (weeks)	20.6 ± 2.4	20.9 ± 2.5
Location of placenta- no. (%)		
Anterior	30 (42%)	40 (57%)
Posterior	42 (58%)	30 (43%)
Quintero stage -- no. (%)		
Stage 1 (abnormal amniotic fluid levels alone)	6 (8%)	5 (7%)
Stage 2 (collapsed bladder in donor)	31 (43%)	31 (44%)
Stage 3 (abnormal Doppler flow in either twin)	34 (47%)	33 (47%)
Stage 4 (hydrops in either twin)	1 (1%)	1 (1%)

At inclusion, the groups were similar with respect to demographic, clinical and ultrasonographic characteristics except for an imbalance in placental location, with

more posterior insertions in the laser group than in the amnioreduction group.<sup>1</sup>

**Table 3 -Subject Accountability**

	S-LPC	Amnioreduction
<b>Subjects Randomized</b>	<b>N=72</b>	<b>N=70</b>
Fetal death prior to treatment	-1	-1
Did not meet study criteria after evaluation	-2	0
Subject withdrew consent	0	-1
<b>Subjects treated</b>	<b>N=69</b>	<b>N=68</b>

### Summary of Results

#### Primary Outcome Measures

The planned interim analysis showed that S-LPC was associated with a significantly higher rate of survival of at least one infant to discharge from the NICU. This outcome was considered to be more clinically relevant than survival at 28 days which was one of the three original primary outcome measures. None of the infants died after being discharged from the NICU, and thus the rate of discharge from the NICU was the same as the rate of survival of at least one twin to 6 months. The rate of survival of at least one twin and clinically significant neurologic complications at six months, as presented in the table, are likely to be representative of those obtained with 7-12 month follow-up as stated in the original primary outcome measures. Since the study was stopped early there was no data provided on the primary outcome measure related to survival at 7-12 months.

**Table 4 – Primary Outcome Measures**

	Laser	Amnioreduction	p-value
Perinatal survival to 28 days	55/72 (76%)	39/70 (56%)	0.009
Survival of at least one twin to at least 6 months	55/72 (76%)	36/70 (51%)	0.002
▪ 1 survivor	29/72 (40%)	18/70 (26%)	
▪ 2 survivors	26/72 (36%)	18/70 (26%)	
Intraventricular hemorrhage (IVH) (grade III or IV)†	2/144 (1%)	8/140 (6%)	0.10**
Donor	2/72 (3%)	2/70 (3%)	1.0
Recipient	0/72	6/70 (9%)	0.02
Cystic periventricular leukomalacia‡	8/144 (6%)	20/140 (14%)	0.02**
Donor	2/72 (3%)	5/70 (7%)	
Recipient	6/72 (8%)	15/70 (21%)	
Blindness *	2/144 (1%)	1/140 (0.71%)	0.576
Deafness	0/144	0/140	1.00

†Severe IVH was defined as ventricular bleeding with dilatation of the cerebral ventricles (grade III) or parenchymal hemorrhage (grade IV)

‡ Cystic periventricular leukomalacia was defined as periventricular densities evolving into cystic lesions (grade III) or extending into the deep white matter and evolving into cystic lesions (grade IV)

\*The reported cases of blindness may represent cases included elsewhere in the table, i.e.,

intraventricular hemorrhage

\*\* This analysis was adjusted for clustering between twins

Overall, the S-LPC subjects had better long-term outcomes than the amnioreduction subjects. However, amnioreduction subjects had better short-term outcomes in the categories pregnancy loss within seven days, PROM within seven days and intrauterine death within seven days of the initial procedure.

**Table 5 - Other Outcome Measures**

	Laser N=72	Amnioreduction N=70	p-value
Gestational age at delivery (no. of pregnancies)			0.003*
< 24 wk	12	8	
24 to <27 wk	9	22	
27 to <32 wk	9	18	
32 to < 33 wk	9	7	
33 to 35 wk	17	11	
≥ 36 wk	16	4	
Median gestational age at delivery (weeks)	33.3	29.0	0.004
Mean birth weight (g)**	1757	1359	< 0.001
Median total volume of amniotic fluid drained and range (mL)†	1725 (500-5500)	3800 (600-18,000)	< 0.001

\*The Chi-square test was used with 5 degrees of freedom.

\*\* These values are based on liveborn infants.

†This data does not include 5 women (3 Laser and 2 Amnioreduction) who did not undergo the assigned procedure.

The relative risk of the death of both fetuses in the S-LPC group compared to the amnioreduction group was 0.63 (95% CI 0.25 to 0.93, p=0.009).

The authors only reported on neonatal neurological morbidity. Neonatal morbidity associated with pulmonary, intestinal, or other organ systems are therefore not presented here.

## XI. RISK/PROBABLE BENEFIT ANALYSIS

Twin-to-Twin Transfusion Syndrome is characterized by shunting of blood from one twin to another through vascular anastomoses within the shared placenta. The recipient gets too much blood, which puts a strain on his cardiovascular system and produces an excessive amount of amniotic fluid in his sac. In contrast the donor twin cannot replace the blood he is shunting to the recipient fast enough and therefore suffers from severe anemia. Also in contrast to the recipient, the donor twin does not get enough blood and may expire from severe anemia. Because the donor twin does not get enough blood, he will not urinate as frequently and there will be too little amniotic fluid. If a donor twin should pass away an acute "reverse" transfusion can

occur from the recipient back to the donor causing the recipient also to expire as his cardiovascular system is unable to process the excessive amount of blood being transfused. Left untreated TTTS is associated with a perinatal mortality rate of up to 90%.<sup>1</sup>

Current treatment interventions include amnioreduction or amniodrainage, amniotic septostomy and selective feticide. These interventions have been associated with significant morbidity and mortality.

Selective laser photocoagulation of the communicating vessels is the one treatment that actually treats the source of the condition by photocoagulating only those vessels involved in the blood shunting between the twins. This procedure specifically targets the communicating vessels involved in the volume transfusion process between the two fetuses by coagulating the unmatched vascular anastomoses. Studies conducted comparing serial amniodrainage to fetoscopic laser surgery have demonstrated the superiority of laser surgery in prolonging gestation, thereby ensuring a more advanced gestational age at delivery of the fetuses and a higher birth weight. Furthermore, they have demonstrated that laser surgery was associated with a higher probability of having one or more twins survive per pregnancy. The Karl Storz Fetoscopy Instruments Sets are specifically designed to facilitate this process and aid in treating this unique group of patients.

Therefore, it is reasonable to conclude that the probable benefit to health from using the Karl Storz Fetoscopy Instrument Sets in TTTS in fetuses whose gestational age is between 16 and 26 weeks outweighs the risk of illness or injury, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment when used as indicated in accordance with the directions for use.

#### XII. PANEL RECOMMENDATION

It was determined that the preclinical and clinical issues raised by this HDE did not require review by the Obstetrics and Gynecology Devices Advisory Panel. Although panel review of this HDE application was not performed, consultation with a panel member was sought during the conduct of this review.

#### XIII. CDRH DECISION

CDRH has determined that, based on the data submitted in the HDE, that the Karl Storz Rigid TTTS Fetoscopy Instrument Set and the Karl Storz Semi-Rigid Fetoscopy Instrument Set will not expose patients to an unreasonable or significant risk or illness or injury, and the probable benefit to health from using the device outweighs the risks of illness or injury, and issued an approval order on March 29, 2006.

#### XIV. APPROVAL SPECIFICATIONS

Directions for use: See the Physician's Labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See Approval Order.

XV. REFERENCES

1. Senet MV, Deprest J, Boulvain M, Paupe A, Winer N, Ville Y. Endoscopic laser surgery versus serial amnioreduction for severe twin-to-twin transfusion syndrome. *N Engl J Med* 2004;351:136-44.
2. Obido AO and Macones GA. Management of twin-twin transfusion syndrome: laying the foundation for future interventional studies. *Twin Research* 2002;5(6):515-20.
3. Lundvall L, Skibsted L, Graem N. Limb necrosis associated with twin-twin transfusion syndrome treated with YAG-laser coagulation. *ACTA Obstetrica et Gynecologica Scandinavica* 1999; 78:349-350)
4. Stone CA, Quinn MW and Saxby PJ. Congenital skin loss following Nd:YAG placental photocoagulation. *Burns* 1998; 24: 275-277.
5. Hayashi S, Haruhiko S, Reiko H, Nakagawa S, Kitagawa M, Miyashaka K, Chiba T, Natori M. Manifestation of mirror syndrome after fetoscopic laser photocoagulation in severe twin-twin transfusion syndrome. *Fetal Diagn Ther* 2006;21:51-54.
6. Quintero RA, Kontonopoulos E, Chmait R, Bornick P, Allen M. Management of twin-twin transfusion syndrome in pregnancies with iatrogenic detachment of membranes following therapeutic amniocentesis and the role of interim amniopatch. *Ultrasound Obstet Gynecol* 2005;26:628-633.